which the Great Lakes States or Tribe demonstrates that application of one or more guidance procedures to the given pollutant are not scientifically defensible." *Id.* at 20,842. The referenced pollutants listed in Table 5 included numerous pollutants not at issue in this case, and did not include the pollutant whole effluent toxicity ("WET").[3] *Id.* EPA further explained the scientific indefensibility exception in the preamble of the Proposed Guidance:

> Section 132.4(g) [later becoming section 132.4(h)] also provides that the Great Lakes States and Tribes may, but are not required to, apply the proposed criteria methodologies and implementation procedures to any pollutant for which the regulatory authority demonstrates that one or more procedures in the Guidance are not scientifically defensible. The reason for this exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures being proposed today may not be technically appropriate. Under these circumstances, EPA wishes to provide sufficient flexibility for permitting authorities to address these pollutants on a case-by-case basis.

Id. at 20,843.

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3. WET is defined as "the aggregate toxic effect of an effluent measured directly by a toxicity test." 40 C.F.R. § 122.2. "The whole effluent approach to toxics control for the protection of aquatic life involves the use of acute and chronic toxicity tests to measure the toxicity of wastewaters." *Technical Support Document For Water Quality-Based Toxics Control*, EPA/505/2-90-001 (March 1991).

On March 23, 1995, after accepting and responding to comments from interested parties, EPA promulgated a final guidance document pursuant to section 118(c)(2)(A) of the Clean Water Act (the "GL Guidance"). *See Final Water Quality Guidance for the Great Lakes System*, 60 Fed. Reg. 15,366 (March 23, 1995). Generally, the GL Guidance

> consists of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that can be allowed to reach the Lakes and their tributaries from all sources; and antidegradation policies and procedures.

60 Fed. Reg. at 15,366. In the introduction of the GL Guidance, EPA referenced an informal EPA document named the *Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID)*, (EPA, March 1995, 820-B-95-001) (the "SID"), stating that "[d]etailed discussion of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance, are provided in" the SID. *Id.* at 15,367. The SID, however, was not promulgated pursuant to the Administrative Procedures Act's rulemaking procedures (5 U.S.C. §§ 551-559), but was drafted as an informal "support document" for the GL Guidance. *See* SID, § DISCLAIMER. In fact, the SID was reviewed only by EPA's Office of Science and Technology. *Id.*

The GL Guidance specifically established minimum WET requirements for the Great Lakes System, including procedures for determining whether wastewater may have the reasonable potential to cause or contribute to a discharge in excess of water quality standards governing WET, and thus must be subjected to effluent discharge limits. 60 Fed. Reg. at 15,378; *see also*, 40 C.F.R. pt. 132, Appendix F, Procedure 6. The GL Guidance requires Great Lakes States to impose effluent limitations, either for WET or for a specific chemical causing the toxicity, if it determines "that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above" any WET criterion specified in the State's water quality standards. 60 Fed. Reg. at 15,423. The GL Guidance sets forth specific mathematical calculations for making WET reasonable potential determinations. *Id.* at 15,423-24.

The GL Guidance provides that States may adopt an alternative implementation procedure for a particular pollutant, if the GL Guidance implementation procedure is not scientifically defensible:

> [T]he final Guidance provides flexibility for State and Tribal adoption and implementation of provisions consistent with the final Guidance in many areas, including the following:
>
> . . .
>
> Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision

> in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision is in § 132.4(h) of the final Guidance.

60 Fed. Reg. at 15,370. Accordingly, EPA formally promulgated the scientific defensibility exception to the GL Guidance at 40 C.F.R. § 132.4(h) ("section 132.4(h)"), which provides as follows:

> For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:
>
> (1) Apply an alternative methodology or procedure acceptable under 40 C.F.R. part 131 when developing water quality criteria; or
>
> (2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

40 C.F.R. § 132.4(h). Unlike the preamble to the Proposed Guidance, section 132.4(h) does not indicate that the scientific defensibility exception is limited only to pollutants identified in the future.

With the GL Guidance in place, section 118(c)(2)(C) of the Clean Water Act requires Great Lakes States to adopt water quality standards, antidegradation policies, and implementation procedures that are consistent with (or as protective as) the GL Guidance for waters within the Great

Lakes System. 33 U.S.C. § 1268(c)(2)(C).[4] To satisfy this requirement, on December 16, 1996, the State of Indiana adopted Great Lakes System water quality standards, antidegradation policies, and implementation procedures, which became effective on February 13, 1997 (the "Indiana Rules"). As part of the adoption of the Indiana Rules, the State of Indiana determined that the GL Guidance procedure for evaluating whether wastewater discharges have the reasonable potential to cause or contribute to an excursion above water quality criteria concerning WET was not scientifically defensible within Indiana.[5] Accordingly, as permitted by section 132.4(h), the State of Indiana elected to implement an alternative procedure to make WET reasonable potential determinations.

On August 4, 2000, after reviewing the submissions of various Great Lakes States, EPA issued an order promulgating a final rule entitled *Identification of Approved and Disapproved Elements of the Great Lakes Guidance Submissions From the States of Michigan, Ohio, Indiana, and Illinois, and Final Rule* (the "EPA Order"). 65 Fed. Reg. 47,864 (Aug. 4. 2000); App. at 19a. The EPA Order approved, conditionally approved, or disapproved various provisions of the Indiana Rules. *Id.* Relevant to this case, EPA

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4. If a Great Lakes State, however, fails to adopt standards, policies, and implementation procedures consistent with the GL Guidance, EPA is required to promulgate them for the State. 33 U.S.C. § 1268(c)(2)(C).

5. Specifically, the State of Indiana submitted information to EPA showing that most of the WET data was below levels that can be quantified, and, therefore, there was insufficient information to validate the assumptions on which the GL Guidance treatment of WET is based.

disapproved Indiana's procedure for determining whether wastewater discharges have the reasonable potential to cause or contribute to an excursion above a WET water quality standard. 65 Fed. Reg. at 47,868-69; App. at 39a-40a.

Proceedings below. IWQC filed a Petition for Review challenging the EPA Order's finding that the Indiana Rules were inconsistent with the GL Guidance.[6] IWQC argued that the State of Indiana had submitted sufficient information and analysis to establish that the WET reasonable potential procedures in the GL Guidance are not scientifically defensible within Indiana. According to section 132.4(h), upon such demonstration, the State of Indiana is permitted to use an alternative implementation procedure to make WET reasonable potential determinations, as long as the procedure is otherwise consistent with federal and state law. IWQC also argued that the WET reasonable potential procedure in the Indiana Rules is consistent with applicable federal and state law.

In response, EPA argued that section 132.4(h) only applies to pollutants identified in the future, citing language in the preamble to the Proposed Guidance that stated "pollutants identified in the future for which some of the methodologies or procedures [in the Guidance] may not be technically appropriate." 58 Fed. Reg. at 20,843. EPA also cited to the informal SID, which states that "[t]he reason for

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6. IWQC originally filed its Petition for Review with the Seventh Circuit on December 18, 2000. IWQC's co-petitioners below filed a Petition for Review with the Sixth Circuit on December 1, 2000. On April 11, 2001, IWQC's Petition for Review was transferred to the Sixth Circuit pursuant to a Motion to Transfer filed by EPA under 28 U.S.C. § 2112(a)(1) and (5). On May 15, 2001, the Sixth Circuit accepted the transfer, consolidating the two cases.

this exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures in the final Guidance may not be technically appropriate." EPA argued that because WET is not a pollutant identified in the future, section 132.4(h) does not allow the State of Indiana to implement an alternative procedure for its WET reasonable potential analysis.

On June 16, 2005, the Sixth Circuit denied IWQC's Petition for Review. *IWQC v. EPA*, 411 F.3d 726, 736 (6th Cir. 2005); App. at 16a. With regard to the scientific indefensibility exception, the court deferred to EPA's interpretation of section 132.4(h):

> But the EPA makes a compelling argument when it points out that the provision allowing alternative schemes was developed because "there may be pollutants identified *in the future* for which some of the methodologies or procedures [in the GL Guidance] may not be technically appropriate. Under these circumstances, EPA wishes to provide sufficient flexibility for permitting to address these pollutants on a case-by-case basis."

Id. (quoting Proposed Guidance, 58 Fed. Reg. at 20,843); App. at 15a-16a. The Sixth Circuit also relied on the SID for the same proposition, that section 132.4(h) only applies to "pollutants identified in the future." *Id.* The Sixth Circuit then concluded that under EPA's interpretation of section 132.4(h), WET discharges were not covered by the scientific indefensibility exception. *Id.* ("WET discharges, which have concerned the EPA for decades, do not fall under the category of 'pollutants identified in the future.' . . . This exception to the Guidance is therefore inapplicable to the petitioners'

regulatory schemes.") *Id.*; App. at 16a. On November 22, 2005, the Sixth Circuit confirmed its ruling and denied IWQC's Petition for Rehearing En Banc. App. at 17a-18a.

REASONS FOR GRANTING THE PETITION

This petition seeks review of whether EPA's interpretation limiting the scope of an unambiguous regulation — section 132.4(h) — is entitled to deference. The decision below that granted deference to EPA's interpretation of section 132.4(h) conflicts with a longstanding body of regulatory law established by this Court and numerous circuit courts, which does not allow a court to defer to such an interpretation where a regulation is clear on its face. That decision, if followed by other courts, would give agencies the unfettered discretion to amend the plain language of regulations through informal methods, without the procedural safeguards established by the Administrative Procedures Act (the "APA"). 5 U.S.C. § 500, *et seq.* Because the Sixth Circuit's decision departed from the accepted and usual course of judicial proceedings, the Court should grant review to clarify and confirm that agency interpretations are not entitled to deference where the regulation at issue is not ambiguous.

THE SIXTH CIRCUIT'S DECISION CONFLICTS WITH WELL-ESTABLISHED ADMINISTRATIVE LAW PROVIDING THAT AN AGENCY INTERPRETATION OF A REGULATION IS NOT ENTITLED TO DEFERENCE WHERE THE REGULATION IS UNAMBIGUOUS ON ITS FACE.

The seminal case of *Chevron U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-44 (1984) established the principle that courts must give effect to an agency's reasonable interpretation of an ambiguous statute. This rule was subsequently extended to apply to the interpretation of ambiguous regulations. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997) (In interpreting a regulation, the Court held that "Because the salary-basis test is a creature of the Secretary's own regulations, his interpretation of it is, under our jurisprudence, controlling unless 'plainly erroneous or inconsistent with the regulation.'") Deferral to an agency's interpretation of a regulation, however, "is warranted only when the language of the regulation is ambiguous." *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). The Court explained the rationale behind this rule:

> To defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation. Because the regulation is not ambiguous on the issue of compelled compensatory time, *Auer* deference is unwarranted.

Id. In other words, where the language selected by the drafters is clear and unequivocal, courts are bound to give effect to the plain meaning of the chosen words. *Id.*; *Norfolk S. Ry.*

Co. v. Shanklin, 529 U.S. 344, 356 (2000); *Wards Cove Packing Corp. v. Nat'l Marine Fisheries Serv.*, 307 F.3d 1214, 1219-20 (9th Cir. 2002); *Navarro v. Pfizer Corp.*, 261 F.3d 90, 103 n. 7 (1st Cir. 2001); *Echevarria v. Chicago Title & Trust Co.*, 256 F.3d 623, 629 (7th Cir. 2001); *Clean Ocean Action v. York*, 57 F.3d 328, 333 (3rd Cir. 1995); *In re: Sealed Case*, 237 F.3d 657, 667 (D.C. Cir. 2001); *Restrepo v. McElroy*, 369 F.3d 627, 638 n. 19 (2d Cir. 2004).

The unambiguous language of section 132.4(h) provides:

> For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:
>
> (1) Apply an alternative methodology or procedure acceptable under 40 C.F.R. part 131 when developing water quality criteria; or
>
> (2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

40 C.F.R. § 132.4(h). Table 5 of 40 C.F.R. part 132 lists 14 pollutants that are specifically excepted from section 132.4(h). 40 C.F.R. part 132 also lists other pollutants that are not included in Table 5, and are, therefore, included within the scope of section 132.4(h). WET is not listed as a pollutant in Table 5, but is otherwise listed as a pollutant in 40 C.F.R. part 132. The only possible interpretation of the plain language of section 132.4(h) is that it applies to all pollutants other than those listed in Table 5. WET is not listed in

Table 5. Accordingly, section 132.4(h) applies to WET. The terms of section 132.4(h) contain no language that limits a State's use of the scientific indefensibility provision only to pollutants identified in the future. There is no ambiguous language that would support an interpretation that the scope of section 132.4(h) is limited to pollutants identified in the future. *See Chickasaw Nation v. United States*, 534 U.S. 84, 90 (2001) (Language is ambiguous if it is "capable of being understood in two or more possible senses or ways.") (quoting Webster's Ninth New Collegiate Dictionary 77 (1985)); *Caminetti v. United States*, 242 U.S. 470, 485 (1917) ("Where the language is plain and admits of no more than one meaning the duty of interpretation does not arise and the rules which are to aid doubtful meanings need no discussion.") The Sixth Circuit should not have deferred to an agency interpretation contrary to the plain language of the regulation.

This well-settled rule of regulatory construction has been applied by other circuit courts to EPA attempts to interpret unambiguous regulations. *See e.g., Clean Ocean Action*, 57 F.3d at 332-33. In that case, the Third Circuit examined EPA's interpretation of its ocean dumping regulations promulgated under the Marine Protection, Research, and Sanctuaries Act ("MPRSA"). *Id.* at 331-32. The MPRSA directed EPA to establish criteria for determining whether to issue permits for the dumping of materials. *Id.* EPA regulations required the performance of tests in certain circumstances to determine whether to issue a permit. *Id.* at 332. EPA refused to conduct these tests, contending that the regulations afforded it discretion to determine whether to conduct tests even when the specified circumstances were present. *Id.* at 332-33. The Third Circuit rejected EPA's position. *Id.* at 333. Specifically, the court found that the

language of EPA's regulation was unambiguous, and, therefore, EPA's interpretation was not entitled to deference. *Id.* The Sixth Circuit's decision directly conflicts with this precedent.

In addition, the means by which EPA attempted to restrict the scope of section 132.4(h) further demonstrate that the Sixth Circuit's decision conflicts with well-established law. Specifically, the decision below relied on an interpretation of section 132.4(h) contained in the SID, an informal EPA guidance document only reviewed by EPA's Office of Science and Technology. However, the SID, having been informally published by EPA without using the rulemaking procedures of the APA, was not entitled to the deference the Sixth Circuit afforded it. *Christensen*, 529 U.S. at 587 ("Interpretations such as those in opinion letters — like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law — do not warrant *Chevron*-style deference."); *see also, Navarro*, 261 F.3d at 103 n.7 (EEOC interpretive guideline was not entitled to deference); *Clean Ocean Action*, 57 F.3d at 333 (EPA's "Green Book" was not entitled to deference because an "agency guideline or directive that conflicts with the plain meaning of a regulation is invalid."); *Echevarria*, 256 F.3d at 629 (court afforded no extra deference to HUD opinion letter and special information booklet). The Sixth Circuit decision to follow the informal statements in the SID conflicts with this established case law. The decision below used the SID, not to interpret ambiguous language, but to create, *de facto*, a new provision that narrows the scope of section 132.4(h). Because it was inconsistent with the plain language of section 132.4(h), the SID, as an informal guidance document, should not have been relied upon as an interpretive device.

Further, the preamble to the draft Proposed Guidance (58 Fed. Reg. at 20,843), was not a proper basis for the Sixth Circuit to rely upon in deferring to EPA's interpretation of section 132.4(h). Although a preamble may be used as an interpretive supplement in certain cases, it cannot be used to contradict unambiguous language. *Yazoo R.R. Co. v. Thomas*, 132 U.S. 174, 188 (1889) (". . . the preamble is no part of the act, and cannot enlarge or confer powers, nor control the words of the act, unless they are doubtful or ambiguous . . ."); *Beard v. Rowan*, 34 U.S. 301, 317 (1835) ("The preamble in the act may be resorted to, to aid in the construction of the enacting clause, when any ambiguity exists."); *Entergy Servs., Inc. v. FERC*, 375 F.3d 1204, 1209 (D.C. Cir. 2004) (". . . FERC correctly notes that 'language in the preamble of a regulation is not controlling over the language of the regulation itself.'") (quoting *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999)). Again, the decision below departed from this established line of cases by using the preamble to a proposed rule to overcome the plain language of the regulation.

The Sixth Circuit decision has created a conflict with deep-rooted case law, which if permitted to stand will allow EPA, as well as other government agencies, to create new regulatory requirements without APA scrutiny where a regulation is unambiguous on its face. Such precedent would undermine well-established cases, starting with *Chevron* and culminating with *Christensen*, which uniformly allow a court to defer to an agency interpretation "only when the language of the regulation is ambiguous." *Christensen*, 529 U.S. at 588. The effect of the Sixth Circuit precedent "would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation," as happened in this case.

Id. The Court should grant review to clarify that agencies (including EPA) cannot controvert the plain language of a federal regulation through their own interpretive devices.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT FILED JUNE 16, 2005

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Nos. 00-4502; 01-3379

NORTHEAST OHIO REGIONAL SEWER DISTRICT; CITY OF CINCINNATI, on behalf of the Metropolitan Sewer District of Greater Cincinnati, Hamilton County, Ohio; CITY OF AKRON, Public Utilities Bureau; CITY OF COLUMBUS, Division of Sewerage & Drainage; CITY OF TOLEDO (00-4502); INDIANA WATER QUALITY COALITION (01-3379),

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

December 1, 2004, Argued
June 16, 2005, Decided
June 16, 2005, Filed

OPINION

RONALD LEE GILMAN, Circuit Judge. A group of public agencies and private companies based in Indiana and Ohio have petitioned this court for a review of a final decision

issued by the United States Environmental Protection Agency (EPA) regarding state regulatory schemes governing toxic discharges into the Great Lakes. For the reasons set forth below, we deny the petitions for review.

I. BACKGROUND

A. Factual background

This litigation arises under the Clean Water Act, the purpose of which is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). Section 402 of the Clean Water Act established the National Pollutant Discharge Elimination System (NPDES), which obligates polluters to obtain permits for their discharges. Each permit issued under NPDES must include restrictions on pollution discharge and, if necessary, water effluent toxicity (WET) limitations. Although the regulations under NPDES allow a permitting authority to impose a WET limitation whenever a discharge has at least a "reasonable potential" to lead to a water quality violation, they do not establish a specific procedure for the permitting authority to follow. The permitting authority is instead required to take into account certain enumerated factors.

In the late 1980s, the governors of the eight states surrounding the Great Lakes entered into an agreement to protect and preserve the environmental integrity of the Great Lakes waters. Congress followed up by enacting the Great Lakes Critical Programs Act of 1990, which amended Section 118 of the Clean Water Act. 33 U.S.C. § 1268. In this amendment, Congress instructed the EPA to promulgate

regulations to ensure that water quality procedures in the states around the Great Lakes would be "no less restrictive" than the already-existing water quality criteria. 33 U.S.C. § 1268(c)(2)(A). Congress also provided that "the Great Lakes States shall adopt water quality standards, antidegredation policies, and implementation procedures for waters within the Great Lakes System which are consistent with such guidance." 33 U.S.C. § 1268(c)(2)(C).

The EPA set forth these rules in a regulation titled the "Final Water Quality Guidance for the Great Lakes System" (the Guidance), found at 60 Fed. Reg. 15,366 (Mar. 23, 1995). Specific provisions of the Guidance govern individual discharges of toxic pollutants into Great Lakes waters. Following the issuance of the Guidance, the eight Great Lakes states were required to adopt and submit to the EPA implementation procedures of their own. The states have the flexibility to create and modify their own regulatory schemes, so long as the net level of protection offered by their provisions match or exceed those promulgated under the Guidance. *See* 40 C.F.R. § 132.5(g)(3). If the states fail to establish regulations consistent with the Guidance, Congress has mandated that the EPA impose its own standards on the states. 33 U.S.C. § 1268(c)(2)(C).

Under the Guidance, the procedures for establishing WET limits are roughly as follows: Samples are taken from a facility's discharge. Marine organisms are then exposed to these samples as well as to control samples, and tests are done to determine what percentage of these organisms die upon exposure. A "toxic unit," which is a quantitative value, is based upon the percentage of deaths that occur. The highest

daily "toxic unit" value measured in the discharge (or, in some cases, the highest weekly value) is then multiplied by a predetermined statistical variable, which depends upon the number of the data points and the variation in results. If the resulting value is greater than the EPA's predetermined criterion, the permitting authority is required to impose a WET limitation.

Indiana submitted its rules to the EPA in late 1997. The EPA subsequently criticized Indiana's proposed procedure because, unlike the Guidance, which used the maximum value from all of the WET tests during the relevant time period, Indiana's procedure would use the geometric mean of all values sampled. In addition, the EPA disapproved of the fact that Indiana's procedure did not employ a statistically based multiplier in its analysis. The EPA thus concluded that Indiana's proposed procedures were inconsistent with the Guidance and issued a final order to that effect on August 4, 2000.

Ohio also submitted its rules to the EPA in late 1997 and, like Indiana, part of its proposal was rejected as being inconsistent with the Guidance. Unlike the Guidance's rigid statistical test, the Ohio test adopted a "weight-of-the-evidence" approach that would require the permitting authority to look to a variety of factors in deciding whether to impose a WET limit. The EPA found that this approach granted too much flexibility to the permitting authority, noting that it would "devalue observed WET test results and would not require a [limit] even where WET test results show observed levels of unacceptable toxicity." *Approved and Disapproved Elements of the Great Lakes Guidance*

Submissions, 65 Fed. Reg. 47864, 47867 (Aug. 4, 2000). It also faulted the fact that Ohio did not employ a statistically based multiplier. The EPA concluded that the procedures were inconsistent with the Guidance in the same final order that it issued regarding the Indiana procedures.

B. Procedural background

On December 1, 2000, approximately four months after the final EPA order was issued, a group of Ohio entities (hereinafter the Ohio petitioners) filed suit in this court challenging the EPA's conclusion that the proposed Ohio rules were inconsistent with the Guidance. A similar group of Indiana petitioners, united under the moniker Indiana Water Quality Coalition (IWQC), filed suit on December 18, 2000 in the United States Court of Appeals for the Seventh Circuit, challenging the EPA's final decision that the Indiana proposed rules were inconsistent with the Guidance. Pursuant to 28 U.S.C. § 2112(a)(1) and (5), the EPA moved to transfer the case to this court, where the Ohio petitioners had already filed a similar petition. The Seventh Circuit granted the EPA's petition on April 16, 2001. This court accepted the transfer on May 15, 2001, consolidating the two actions into the present case.

II. ANALYSIS

A. Standard of review

This case is governed by the Federal Administrative Procedure Act (APA), 5 U.S.C. § 706. Under the APA, courts will not set aside a final agency action unless it is found to

be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

This standard is deferential. "Even when an agency explains its decision with less than ideal clarity, a reviewing court will not upset the decision on that account if the agency's path may reasonably be discerned." *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 124 S. Ct. 983, 1006, 157 L. Ed. 2d 967 (2004) (quotation marks omitted). In considering whether an agency rule is "arbitrary and capricious," we may consider whether

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given.

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1982) (quotation marks omitted). This court has also noted that it will "defer in large part to EPA's scientific findings." *BP Exploration & Oil v. EPA*, 66 F.3d 784, 792 (6th Cir. 1995). Although the court's review is to be "searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the

agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 28 L. Ed. 2d 136, 91 S. Ct. 814 (1971), *questioned on other grounds by Califano v. Sanders*, 430 U.S. 99, 105, 51 L. Ed. 2d 192, 97 S. Ct. 980 (1977).

B. The scope of petitioners' challenge

The EPA asserts at the outset that this consolidated case is nothing more than an attempt by the petitioners to have this court review the validity of the Guidance itself, as opposed to a review of the Indiana and Ohio regulatory schemes. Under the Clean Water Act, any petitions for judicial review of the Guidance, which was enacted in 1995, had to have been filed within 120 days of its promulgation. 33 U.S.C. § 1369(b)(1). If the EPA is correct, therefore, then we would have to dismiss the present case as a result of it being filed nine years too late.

We find this argument unconvincing. The petitioners have repeatedly conceded that their challenge is limited to the reasonableness of the EPA's finding that the Indiana and Ohio implementation procedures are inconsistent with the Guidance. Although the EPA is correct in noting that many of the petitioners' arguments originate in the language of the Guidance, this is because the Guidance provides the frame of reference to which the Indiana and Ohio procedures must be compared. That the Guidance is held to some degree of scrutiny does not necessarily make this action a challenge to its validity. To the contrary, petitioners' briefs nowhere suggest that they contest the legitimacy of the Guidance. Dismissing this case on the basis that it is an overbroad challenge to the Guidance itself would thus be inappropriate.

C. Res judicata and collateral estoppel arguments

The EPA further argues that the petitioners are barred by the doctrines of res judicata and collateral estoppel from challenging the Guidance on account of *American Iron & Steel Institute v. EPA*, 325 U.S. App. D.C. 76, 115 F.3d 979 (D.C. Cir. 1997), in which the Court of Appeals for the District of Columbia rejected the claims of various petitioners, including the petitioners in the present case, that the Guidance was an abuse of the EPA's authority. It argues that the petitioners should have raised in that case any challenges they had about the "validity and level of protection afforded" by the Guidance, and that "issue preclusion" bars the relitigation of any claims in that case. The EPA concludes that "only the reasonableness of EPA's finding that Indiana and Ohio's implementation procedures were not as protective to the environment as the Guidance's corresponding procedure falls within the scope of this proceeding."

The petitioners, however, do not challenge the EPA's position on the scope of this case. They admit that the present suit is, indeed, nothing more than a challenge of the narrow administrative ruling regarding the Indiana and Ohio implementation procedures. The Ohio petitioners even observe that "not only do the Ohio Petitioners not seek to 'revisit' the holding of [*American Iron*], they actually rely upon that case and cite to it in their Opening Brief for one of the very principles that EPA erroneously claims to be under attack." Furthermore, as discussed above, the present suit cannot be appropriately deemed to be a suit against the validity of the Guidance. Nothing in the briefs of the petitioners suggests otherwise. Because the EPA has little

support for its conclusion that the petitioners are, in fact, challenging the legitimacy of the Guidance as was done in *American Iron*, we decline to dismiss the case under the theories of either res judicata or collateral estoppel.

D. The Indiana and Ohio WET tests

IWQC and the Ohio petitioners argue that the EPA erred when it concluded that their regulatory schemes were inconsistent with the Guidance. All of the parties agree that to be "consistent with" the Guidance, the regulatory scheme in question must be at least as protective of the environment as the Guidance. *See* 40 C.F.R. 132.5(g)(3) ("The Great Lakes States . . . may adopt provisions that are more protective than those contained in this part."); *American Iron*, 115 F.3d at 988 (deferring to the EPA's assessment that to be "consistent with" the Guidance, the regulatory regime in question must be "as protective as" the Guidance itself). Accordingly, both IWQC and the Ohio petitioners assert that the proposals submitted by their respective states are at least as protective of the environment as the Guidance, if not more so. Because of variations between the Indiana and Ohio regulations, each will be examined in turn.

1. Indiana's regulatory scheme

Indiana's proposed scheme differs from the Guidance in two key ways. First, under Indiana's proposal, "toxic unit levels" required to assess water toxicity are measured using a geometric mean of tested values. The EPA's Guidance, by contrast, uses a maximum tested value to ascertain toxicity, a value that is, by mathematical definition, greater than the

geometric mean. Under Indiana's system, then, a facility's effluent would have to be consistently higher than the mean before a permitting authority would impose a WET limit. Second, the Indiana scheme does not employ the statistical multiplier called for by the Guidance, using instead its own independently derived factor. IWQC asserts that Indiana's scheme is more protective of the environment than the Guidance.

The EPA, however, observed in its final decision that Indiana's procedure, which calls for using a mean value of toxicity, "lessens the impact of observed toxicity on the limitation calculation and fails to account for the reasonable possibility that effluent may exceed the level observed in the test because sampling did not coincide with periods of maximum toxicity." ***Approved and Disapproved Elements of the Great Lakes Guidance Submissions***, 65 Fed. Reg. 47864, 47868 (Aug. 4, 2000). A maximum value taken from a sample will necessarily be greater than the geometric mean of the sample.

IWQC also argues that the EPA erred because its "analysis was based on a review of only one small part of Indiana's WET procedures: the use of a geometric mean of the measured effluent values." In reviewing the EPA's analysis, IWQC "sees no indication that EPA has conducted a holistic review of Indiana's WET procedures and compared them to EPA's procedure, as the EPA Guidance contemplates." IWQC then points to numerous provisions in the proposed Indiana rules that, according to its brief, make the scheme more protective than the Guidance.

But there is no reason to believe that the EPA acted in an arbitrary or capricious manner in evaluating the Indiana regulatory scheme. The EPA points to a long list of correspondence in which it considered and commented on various aspects of Indiana's proposal. It noted, for example, the fact that Indiana would "require multiple failures" of a toxicity test before a WET limit could be imposed. EPA's Analysis of Steps Taken By Indiana in Response to EPA's 90-Day Letter 9 (July 31, 2000). The EPA also considered, and rejected, the argument that Indiana's catch-all rule, which would allow a permitting authority to "exercise best professional judgment" to enact WET limits, would correct what the EPA viewed as the deficiencies in the rest of the scheme. *Id.* at 10. This catch-all provision, the EPA noted, "is not a substitute for having a reasonable potential procedure that is as protective" as the Guidance. *Id.* IWQC's charge that the EPA failed to view the proposed regulatory scheme in its entirely is therefore unpersuasive and does not demonstrate that the EPA acted arbitrarily or capriciously.

In sum, the EPA acted rationally and on the basis of considerable evidence when it rejected Indiana's regulatory scheme. Given that Indiana's averaging of toxicity will call for fewer WET limits than a system using maximum values, the EPA's conclusion that the state's scheme would be less protective of the environment was far from being arbitrary or capricious. Because the "agency's path may reasonably be discerned," *Alaska Dep't of Envtl. Conservation*, 124 S. Ct. at 1006, there is no basis for us to grant IWQC's petition for review.

Appendix A

2. Ohio's regulatory scheme

Under Ohio's proposed regulations, the permitting authority must take into account a variety of data on the toxicity of the discharge before issuing a permit or establishing a WET limit. The factors to be considered under this "weight of the evidence" standard include the "magnitude of discharge," the "degree and type of effects," the "quality and quantity of each type of data," and "other relevant factors." Only if the discharge in question meets a variety of criteria will WET limits be imposed. The Ohio petitioners argue that this system, with its comprehensive approach to water quality, is more protective of the environment than the imposition of the statistical multiplier required by the Guidance.

Adopting Ohio's "weight of the evidence" approach, however, necessarily grants the permitting authority wide discretion not afforded by the Guidance. The EPA can rationally read Ohio's rule as failing to provide the permitting authority with guidance on how to weigh the various factors. This discretion arguably makes the Ohio regulatory scheme less protective than the Guidance, in which a statistically determined multiplier is used to determine toxicity.

Ohio's regulatory scheme further limits the permitting authority from imposing a WET limit in the absence of "biological data," except where "[1] the maximum observed toxicity value is at least three times greater than the expected toxicity limit, [2] the average toxicity exceeds one third the expected effluent limit, [3] and more than 30 percent of the test results exceed a projected wasteload allocation."

Appendix A

Approved and Disapproved Elements of the Great Lakes Guidance Submissions, 65 Fed. Reg. 47864, 47867 (Aug. 4, 2000). The Ohio petitioners concede that this provision may produce results that are "less restrictive than the Guidance." But this fact, they argue, is balanced out because "if the data set is large, . . . Ohio's procedure will require a WET limit where the [Guidance] would not." They further point out that "the [Guidance] will not require a limit even if the average values are much higher than those that Ohio considers to be significant." Ultimately, they argue, the EPA's rejection of this scheme was arbitrary and capricious because the "adoption of a more protective element in one provision may be used to offset a less protective element in the same provision." 40 C.F.R § 132.5(g)(3).

The Ohio petitioners concede, however, that their proposed scheme would allow certain toxic discharges to go unregulated in instances where no "biological data" was available. "Ohio's procedure," the EPA concluded, "would not require a reasonable potential finding even where testing has shown actual, observed toxicity. This is clearly inconsistent with [the Guidance.]" *Approved and Disapproved Elements of the Great Lakes Guidance Submissions*, 65 Fed. Reg. 47864, 47867 (Aug. 4, 2000). Because this provision allows pollution where the Guidance would not, the EPA's final action disapproving the regulatory scheme can hardly be considered arbitrary or capricious.

Moreover, the Ohio petitioners' argument that their "weight of the evidence" approach might be more protective than the Guidance in certain hypothetical situations is unpersuasive. The fact remains that Ohio's scheme "fails to

require a limit even in cases of observed toxicity." *Id.* In its final ruling, the EPA identified this weakness as a significant and determinative flaw in the regulatory scheme. It therefore had little need to address the hypothetical situations where the Ohio scheme might be marginally more protective than the Guidance.

The Ohio petitioners are correct in their observation that there is no discussion of the Ohio scheme's more protective elements in the EPA's final disapproval. But this fact alone does not make the EPA's final agency decision arbitrary or capricious. To the contrary, the tone of the EPA's final decision indicates that the Ohio procedure allowing toxic discharges is so antithetical to the very goal of the Guidance that the more protective provisions would have been insufficient to neutralize its effects.

In sum, we find nothing in the record indicating that the EPA acted in an arbitrary or capricious manner in rejecting Ohio's proposed scheme as inconsistent with the Guidance. The Ohio petitioners have simply not met their burden of establishing sufficient grounds to set aside the EPA's final action.

E. The "scientifically indefensible" exception

The Guidance provides that

> for any pollutant . . . for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall: (1) Apply an

> alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or (2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

40 C.F.R. § 132.4(h). IWQC and the Ohio petitioners contend that the system of WET testing espoused by the Guidance is "not scientifically defensible" because of the huge variation introduced by taking only maximum tested values and by utilizing an independent statistical multiplier. They argue that their schemes are appropriate alternatives sanctioned by the Guidance.

The EPA responds by submitting that the petitioners are in effect making a wholesale challenge to the Guidance, a position that is barred both by the statute of limitations and by *American Iron & Steel Institute v. EPA*, 325 U.S. App. D.C. 76, 115 F.3d 979 (D.C. Cir. 1997). We again find the EPA's argument unpersuasive. The petitioners do not challenge the applicability of the Guidance generally; they instead argue that § 132.4(h) allows them to adopt an alternative scheme should they be able to prove that the WET-testing provision provided by the Guidance is scientifically indefensible.

But the EPA makes a compelling argument when it points out that the provision allowing alternative schemes was developed because "there may be pollutants identified *in the future* for which some of the methodologies or procedures [in the Guidance] may not be technically appropriate. Under these circumstances, EPA wishes to provide sufficient

flexibility for permitting to address these pollutants on a case-by-case basis." *Proposed Water Quality Guidance*, 58 Fed.Reg. 20802, 20843 (Apr. 16, 1993) (emphasis added); *see also* EPA, Water Quality Guidance for the Great Lakes System: Supplementary Information Document, EPA-820-B-95-00158 (Mar. 1995) ("The reason for this exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures in the final Guidance may not be technically appropriate.") Moreover, the EPA notes that this exception for scientific indefensibility was intended to be "applied to a specific situation," *id.*, in one or more sites, not to a sweeping alternative regulatory scheme.

WET discharges, which have concerned the EPA for decades, do not fall under the category of "pollutants identified in the future." The "scientific indefensible" exception was not designed to apply to such run-of-the-mill discharges, but rather only on a case-by-case basis if, for whatever reason, applying the Guidance would be inappropriate. This exception to the Guidance is therefore inapplicable to the petitioners' regulatory schemes.

III. CONCLUSION

For all of the reasons set forth above, we deny the petitions for review.

APPENDIX B — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT DENYING PETITIONS FOR REHEARING FILED NOVEMBER 22, 2005

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Nos. 00-4502/01-3379

NORTHEAST OHIO REGIONAL SEWER DISTRICT, ET AL.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

November 22, 2005, Filed

JUDGES: BEFORE: DAUGHTREY and GILMAN, Circuit Judges; and RICE,* District Judge.

ORDER

The court having received two petitions for rehearing en banc, and the petitions having been circulated not only to

* Hon. Walter H. Rice, Senior United States District Judge for the Southern District of Ohio, sitting by designation.

the original panel members but also to all other active** judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petitions for rehearing have been referred to the original panel.

The panel has further reviewed the petitions for rehearing and concludes that the issues raised in the petitions were fully considered upon the original submission and decision of the cases. Accordingly, the petitions are denied.

ENTERED BY ORDER OF THE COURT

** Judge Moore recused herself from participation in this ruling.

APPENDIX C — RELEVANT RULES AND REGULATIONS

FEDERAL REGISTER

Vol. 65, No. 151

Rules and Regulations

ENVIRONMENTAL PROTECTION AGENCY (EPA)

40 CFR Part 132

[FRL-6846-3]

Identification of Approved and Disapproved Elements of the Great Lakes Guidance Submissions From the States of Michigan, Ohio, Indiana, and Illinois, and Final Rule

DATE: Friday, August 4, 2000

ACTION: Final rule.

SUMMARY: EPA published the final Water Quality Guidance for the Great Lakes System (the Guidance) on March 23, 1995. Section 118(c) of the Clean Water Act (CWA) requires the Great Lakes States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania and Wisconsin to adopt within two years of publication of the final Guidance (i.e., March 23, 1997) minimum water quality standards, antidegradation policies and implementation procedures that are consistent with the Guidance, and to submit them to EPA for review and approval. Each of the Great Lakes States made those submissions.

Appendix C

Today, EPA is taking final action on the Guidance submissions of the States of Michigan, Ohio, Indiana and Illinois. EPA's final action consists of approving those elements of the States' submissions that are consistent with the Guidance, disapproving those elements that are not consistent with the Guidance, and specifying in a final rule the elements of the Guidance that apply in the portion of each State within the Great Lakes basin where a State either failed to adopt required elements or adopted elements that are inconsistent with the Guidance. EPA is separately taking final action on the Guidance submissions of the States of Minnesota, New York, Pennsylvania and Wisconsin.

EFFECTIVE DATE: September 5, 2000.

* * *

SUPPLEMENTARY INFORMATION:

I. Discussion

A. Potentially Affected Entities

Entities potentially affected by today's action are those discharging pollutants to waters of the United States in the Great Lakes System in the States of Michigan, Ohio, Indiana and Illinois. Potentially affected categories and entities include:

Category	Examples of potentially affected entities
Industry	Industries discharging to waters within the Great Lakes System as defined in 40 CFR 132.2 in the States identified above.
Municipalities	Publicly-owned treatment works discharging to waters within the Great Lakes System as defined in 40 CFR 132.2 in the States identified above.

Appendix C

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected. This table lists the types of entities that EPA believes could be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility may be affected by these final actions, you should examine the definition of "Great Lakes System" in 40 CFR 132.2 and examine 40 CFR 132.2 which describes the Part 132 regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT section.**

B. Background

On March 23, 1995, EPA published the Guidance. *See* 60 FR 15366 (The term "Guidance" as used below refers to the regulation promulgated by EPA on March 23, 1995 and codified at 40 CFR Part 132). The Guidance establishes minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania and Wisconsin. Specifically, the Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provides methodologies to derive numeric criteria for additional pollutants discharged to these waters. The Guidance also contains minimum implementation procedures and an antidegradation policy.

Appendix C

Soon after being published, the Guidance was challenged in the U.S. Court of Appeals for the District of Columbia Circuit. On June 6, 1997, the Court issued a decision upholding virtually all of the provisions contained in the 1995 Guidance. ***American Iron and Steel Institute, et al. v. EPA (AISI)***, 115 F.3d 979 (D.C. Cir. 1997). The Court vacated the human health criterion for polychlorinated biphenyls (PCBs) and the acute aquatic life criterion for selenium, and the provisions of the Guidance "insofar as it would eliminate mixing zones for [BCCs] and impose [WQBELs] upon internal facility waste streams." 115 F.3d at 985. On October 9, 1997, EPA published a notice revoking the PCB human health criteria pursuant to the Court's decision. 62 FR 52922. On April 23, 1998, EPA published a second notice amending the 1995 Guidance to remove the BCC mixing zone provisions from 40 CFR Part 132 (found in Procedure 3.C. of Appendix F) and to remove language in the Pollutant Minimization Program provisions (Procedure 8.D. of Appendix F) that might imply that permitting authorities are required to impose WQBELs on internal waste streams or to specify control measures to meet WQBELs. 63 FR 20107. On June 2, 2000, EPA published a third notice withdrawing the acute criteria for selenium. 65 FR 35283.

40 CFR 132.4 requires the Great Lakes States to adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System consistent with the Guidance or be subject to EPA promulgation. 40 CFR 132.5(d) provides that, where a State makes no submission to EPA, the Guidance shall apply to discharges to waters in that State upon EPA's publication of a final rule indicating the effective date of the Part 132 requirements in that jurisdiction.

Appendix C

On July 1, 1997, the National Wildlife Federation filed suit alleging that EPA had a non-discretionary duty to promulgate the Guidance for any State that failed to adopt standards, policies and procedures consistent with the Guidance. *National Wildlife Federation* v. *Browner*, Civ. No. 97-1504-HHK (D.D.C.). EPA negotiated a consent decree providing that the EPA Administrator must sign, by February 27, 1998, a Federal Register notice making Part 132 effective in any State in the Great Lakes Basin that failed to make a submission to EPA by that date under 40 CFR Part 132. However, all of the Great Lakes States made complete submissions to EPA on or before the February deadline. On March 2, April 14, April 20 and April 28, 1998, EPA published in the Federal Register notices of its receipt of each of the States' Great Lakes Guidance submissions and a solicitation of public comment on the National Pollutant Discharge Elimination System (NPDES) portions of those submissions. 63 FR 10221; 63 FR 18195; 63 FR 19490; 63 FR 23285.

40 CFR 132.5(f) provides that, once EPA completes its review of a State's submission, it must either publish notice of approval of the State's submission in the Federal Register or issue a letter notifying the State that EPA has determined that all or part of its submission is inconsistent with the CWA or the Guidance, and identify any changes needed to obtain EPA approval. If EPA issues a letter to the State making findings of inconsistencies, the State then has 90 days to make the necessary changes. If the State fails to make the necessary changes, EPA must publish a notice in the Federal Register identifying the approved and disapproved elements of the submission and a final rule identifying the provisions of the Guidance that will apply to discharges within the State.

Appendix C

On November 1 1999, the National Wildlife Federation and the Lake Michigan Federation filed suit alleging that EPA had a non-discretionary duty to take action on the Great Lakes States' Guidance submissions. *National Wildlife Federation* v. *Browner*, Civ. No. 99-3025-HHK (D.D.C.). EPA negotiated a consent decree providing that EPA must sign Federal Register notices by July 31, 2000, taking the action required by 40 CFR 132.5 on the Guidance submissions of the States of Illinois, Indiana, Michigan, Minnesota, Ohio and Pennsylvania; and Federal Register notices by September 29, and October 31, 2000, taking the action required by 40 CFR 132.5 on the Guidance submissions of the States of New York and Wisconsin, respectively. Today's Federal Register notice fulfills EPA's obligations under that Consent Decree with respect to the States of Michigan, Ohio, Indiana and Illinois. EPA is separately taking final action with respect to the States of Minnesota, New York, Pennsylvania and Wisconsin. EPA notes that each of the States' Guidance submissions may contain provisions that revise its NPDES program or water quality standards in areas or with respect to regulated entities not covered by the Guidance. EPA is not taking action at this time to either approve or disapprove any such provisions.

EPA has conducted its review of the States' submissions in accordance with the requirements of Section 118(c)(2) of the CWA and 40 CFR Part 132. Section 118 requires that States adopt policies, standards and procedures that are "consistent with" the Guidance. EPA has interpreted the statutory term "consistent with" to mean "as protective as" the corresponding requirements of the Guidance. Thus, the Guidance gives States the flexibility to adopt requirements

that are not the same as the Guidance, provided that the State's provisions afford at least as stringent a level of environmental protection as that provided by the corresponding provision of the Guidance. In making its evaluation, EPA has considered the language of each State's standards, policies and procedures, as well as any additional information provided by the State clarifying how it interprets or will implement its provisions.

Where EPA has promulgated a final rule that identifies a provision of the Guidance that shall apply in a State, EPA explains below its reasons for concluding that the State failed to adopt requirements that are consistent with the Guidance. Additional explanation of EPA's conclusions are contained in EPA's correspondence with each State (identified in relevant sections below) where EPA initially identified inconsistencies in the States's submission. Notice of the availability of each of these letters was published in the Federal Register and EPA has considered all public comments received regarding any conclusions as to whether a State had adopted provisions consistent with the Guidance.

In this proceeding, EPA has reviewed the States' submissions to determine their consistency with 40 CFR Part 132. EPA has not reopened Part 132 in any respect, and today's action does not affect, alter or amend in any way the substantive provisions of Part 132. To the extent any members of the public commented during this proceeding that any provision of Part 132 is unjustified as a matter of law, science or policy, those comments are outside the scope of this proceeding.

Appendix C

With regard to those elements of the State submissions being approved by EPA, EPA is approving those provisions as amendments to each State's NPDES permitting program under Section 402 of the CWA and as revisions to each State's water quality standards under Section 303 of the CWA. Today's notice identifies those approved elements. Additional explanations of EPA's review of and conclusions regarding the States' submissions, including the specific State provisions that EPA is approving, are contained in the administrative record for today's actions in documents prepared for each State entitled "[particular State] Provisions Being Approved as Being Consistent With the Guidance," "Analysis of Whether [the particular State] Has Adopted Requirements Consistent With the Guidance" and "Analysis of Steps Taken By [the particular State] in Response to EPA's 90-Day Letter."

C. Today's Final Actions

1. The State of Michigan

On June 30 and August 16, 1999, EPA issued letters notifying the Michigan Department of Environmental Quality (MDEQ) that, while the State of Michigan had generally adopted requirements consistent with the Guidance, EPA concluded that portions of the rules adopted by the State were not consistent with corresponding provisions of the Guidance. On September 14, 1999, EPA published in the Federal Register a notice of and solicitation of public comment on its June 30 and August 16, 1999, letters. 64 FR 49803. EPA has completed its review of the State of Michigan's response to, and all public comments on, the June

30 and August 16, 1999, letters, and has determined that, with one exception described below, Michigan has adopted requirements consistent with all aspects of the Guidance. Specifically, Michigan has adopted requirements consistent with, and EPA is therefore approving those elements of the State's submissions which correspond to: the definitions in 40 CFR 132.2; the water quality criteria for the protection of aquatic life, human health and wildlife in tables 1-4 of Part 132; the methodologies for development of aquatic life criteria and values, bioaccumulation factors, human health criteria and values and wildlife criteria in Appendices B-D; the antidegradation policy in Appendix E; and, with one exception, the implementation procedures in Appendix F. As explained more fully below, Michigan has not adopted requirements consistent with the provisions for determining reasonable potential and establishing water quality based effluent limitations for whole effluent toxicity set forth in Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F.

EPA's June 30, 1999, letter concluded that some of the provisions that EPA is now approving authorized the State to act consistent with the Guidance, but provided inadequate assurance that the State would exercise its discretion consistent with the Guidance. Subsequent to that letter, MDEQ provided additional materials, including an Addendum to its Memorandum of Agreement with EPA regarding the State's approved NPDES program in which MDEQ commits to always exercise its discretion under those provisions in a manner consistent with the Guidance. Pursuant to 40 CFR 123.44(c)(3) and 123.63(a)(4), the State is required to comply with commitments made in its

Memorandum of Agreement (MOA) or risk EPA objection to permits and even program withdrawal. These materials have demonstrated to EPA that the State will implement its program (with one exception identified below) consistent with the Guidance. The specific provisions that EPA is approving, and EPA's full rationale for approving these provisions, are set forth in the documents entitled "Michigan Provisions Approved as Being Consistent With the Guidance," "Analysis of Whether Michigan Has Adopted Requirements Consistent With the Guidance" and "Analysis of Steps Taken By Michigan in Response to EPA's 90-Day Letter" included in the record for this action.

EPA has determined that Michigan's provisions at R 323.1219(4) for determining reasonable potential for a discharge to cause or contribute to an exceedance of Michigan's whole effluent toxicity requirements are inconsistent with Section D of Procedure 6 in Appendix F to 40 CFR Part 132. The Guidance procedure for evaluating reasonable potential for whole effluent toxicity (WET) is based on comparing a projected 95th percentile WET value at a 95 percent confidence level with the acute and chronic WET criteria after accounting for any available dilution. This conservative approach is designed to ensure that WQBELs are imposed when there is a reasonable potential for toxicity, taking into account the effluent variability and the size of the data set, even if no toxicity has actually been observed.

In evaluating State reasonable potential procedures for WET, EPA looked for an equivalent level of protection to that provided by the Guidance procedure. In the case of a procedure to determine when a WQBEL is needed, one

important consideration is whether the alternative procedure would indicate the need for a WQBEL in similar situations to those that would trigger a WQBEL under Section D of Procedure 6.

In most cases where there is quantifiable effluent data, EPA's procedure will project an effluent value greater than the maximum observed value to characterize the reasonable worst case effluent. Michigan's procedures for determining WET reasonable potential are based on comparisons of preliminary effluent limits to average effluent toxicity values (with further possible adjustment based on the frequency of failures), rather than comparisons of preliminary effluent limits to maximum effluent toxicity values multiplied by factors to account for effluent variability and size of the data set as required by Paragraph D of Procedure 6 of the Guidance. Michigan's use of the average effluent toxicity value will, except in highly unusual circumstances, be lower than the maximum toxicity value multiplied by the factors to account for effluent variability set forth in the Guidance. Indeed, in certain circumstances, Michigan's procedure would not require a reasonable potential finding even where testing has shown actual, observed toxicity. This is clearly inconsistent with Section D of Procedure 6.

EPA notes that Paragraph 1 of Section C of Procedure 6 requires that WQBELs be imposed whenever the WET reasonable potential procedures in Section D of Procedure 6 show that there is reasonable potential that a discharge will cause or contribute to causing an excursion above a State's numeric WET criterion or narrative criterion. Michigan's R. 323.1219(2) also provides that WQBELs shall be imposed

whenever the WET reasonable potential procedures in Michigan's R. 323.1219(4) show reasonable potential. As discussed above, however, Michigan's WET reasonable potential rules are not consistent with the Guidance. Because R.323.1219(2) links establishment of WQBELs for WET to a finding of reasonable potential under procedures that EPA has determined are not consistent with Section D of Procedure 6 (i.e., the procedures in R. 323.1219(4)), R.323.1219(2) is not consistent with Paragraph 1 of Section C of Procedure 6.

EPA, therefore, disapproves of R. 323.1219 (2) and (4), and has determined that Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F to 40 CFR Part 132 shall apply for discharges into the Great Lakes System in the State of Michigan.

EPA understands that MDEQ intends to initiate rulemaking to revise its regulations to insure that the State's WET reasonable potential provisions are consistent with the Guidance. EPA will work closely with MDEQ to insure that its revised regulations will be consistent with the Guidance. MDEQ will then submit its revised regulations to EPA for approval pursuant to 40 CFR 123.62 as a revision to its NPDES program and, upon EPA approval of those revisions, EPA will revise its regulations so that Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F to 40 CFR Part 132 will no longer apply to discharges into the Great Lakes System in the State of Michigan. EPA also notes that, based upon Michigan's adoption of criteria consistent with the Guidance, EPA intends, in a separate action in the future, to remove Michigan from the list of States specified at

40 CFR 131.36 for which EPA has promulgated specific criteria under Section 304(a) of the Clean Water Act.

2. The State of Ohio

On June 30 and August 16, 1999, EPA issued letters notifying the Ohio Environmental Protection Agency (OEPA) that, while the State of Ohio had generally adopted requirements consistent with the Guidance, EPA concluded that portions of the rules adopted by the State were not consistent with corresponding provisions of the Guidance. On September 14, 1999, EPA published in the Federal Register a notice of and solicitation of public comment on its June 30 and August 16, 1999, letters. 64 FR 49803. EPA has completed its review of the State of Ohio's response to, and all public comments on, the June 30 and August 16, 1999, letters, and has determined that, with only one exception described below, Ohio has adopted requirements consistent with all aspects of the Guidance. Specifically, Ohio has adopted requirements consistent with and EPA is therefore approving those elements of the State's submissions which correspond to, the definitions in 40 CFR 132.2; the water quality criteria for the protection of aquatic life, human health and wildlife in tables 1-4 of Part 132; the methodologies for development of aquatic life criteria and values, bioaccumulation factors, human health criteria and values and wildlife criteria in Appendices B-D; the antidegradation policy in Appendix E; and, with one exception, the implementation procedures in Appendix F. As explained more fully below, Ohio has not adopted requirements consistent with the provisions for determining reasonable potential and establishing water quality based effluent limitations for whole

effluent toxicity set forth in Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F.

EPA's June 30, 1999, letter concluded that some of the provisions that EPA is now approving authorized the State to act consistent with the Guidance, but provided inadequate assurance that the State would exercise its discretion consistent with the Guidance. Subsequent to that letter, OEPA provided additional materials, including an Addendum to its Memorandum of Agreement with EPA regarding the State's approved NPDES program in which OEPA commits to always exercise its discretion under those provisions in a manner consistent with the Guidance. Pursuant to 40 CFR 123.44(c)(3) and 123.63(a)(4), the State is required to comply with commitments made in its MOA or risk EPA objection to permits and even program withdrawal. These materials have demonstrated to EPA that the State will implement its program (with one exception identified below) consistent with the Guidance. The specific provisions that EPA is approving, and EPA's full rationale for approving these provisions, are set forth in the documents entitled "Ohio Provisions Approved as Being Consistent With the Guidance," "Analysis of Whether Ohio Has Adopted Requirements Consistent With the Guidance" and "Analysis of Steps Taken By Ohio in Response to EPA's 90-Day Letter."

EPA has determined that Ohio's procedure at OAC 3745-33-07(B) for determining reasonable potential for a discharge to cause or contribute to an exceedance of Ohio's whole effluent toxicity requirements are inconsistent with Section D of Procedure 6 in Appendix F to 40 CFR Part 132. Ohio's procedure is based on consideration of a wide range of

available data, including the number of tests performed, the magnitude and frequency of toxicity exhibited by the effluent and available biological data. Ohio's procedure is not consistent with the Guidance because rather than provide safety factors to be applied to observed WET data as does Procedure 6, they apply factors that devalue observed WET test results and would not require a WQBEL even where WET test results show observed levels of unacceptable toxicity.

Specifically, where biological data are unavailable to corroborate effluent toxicity data, Ohio's procedures generally do not require establishment of a WQBEL unless the maximum observed toxicity value is at least three times greater than the expected toxicity limit, the average toxicity exceeds one-third the expected effluent limit, and more than 30 percent of the test results exceed a projected wasteload allocation. Where biological data are present to corroborate effluent data that a toxicity problem exists, Ohio's procedure would allow a permit writer to consider WET data at full value (*i.e.*, compare the maximum observed WET result to the expected toxicity limit), but it also requires the permit writer, in determining whether a WQBEL is needed, to weigh factors related to a minimum frequency of actual exceedances and a comparison of the average of WET test results to a percentage of the expected toxicity limit similar to those that must be considered when only WET data are available. Because these procedures devalue toxicity results and fail to require a limit even in cases of observed toxicity, Ohio's procedure would not require a reasonable potential finding even where testing has showed actual, observed toxicity. This is clearly inconsistent with Section D of Procedure 6.

Appendix C

As discussed above with respect to Michigan, Paragraph 1 of Section C of Procedure 6 requires that WQBELs be imposed whenever the WET reasonable potential procedures in Section D of Procedure 6 show that there is reasonable potential that a discharge will cause or contribute to causing an excursion above a State's numeric WET criterion or narrative criterion. Ohio's rules at OAC 3745-33-07(B)(2) provide that WQBELs shall be imposed whenever the WET reasonable potential procedures in Ohio's rules at OAC 3745-33-07(B) show reasonable potential. Because OAC 3745-33-07(B)(2) links establishment of WQBELs for WET to a finding of reasonable potential under procedures that EPA has determined are not consistent with Section D of Procedure 6 (*i.e.*, the procedures in OAC 3745-33-07(B)), OAC 3745-33-07(B)(2) is not consistent with Paragraph 1 of Section C of Procedure 6.

EPA, therefore, disapproves of OAC 3745-33-07(B), and has determined that Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F to 40 CFR Part 132 shall apply for discharges into the Great Lakes System in the State of Ohio.

3. The State of Indiana

On August 16, 1999, EPA issued a letter notifying the Indiana Department of Environmental Management (IDEM) that, while the State of Indiana had generally adopted requirements consistent with the Guidance, EPA concluded that portions of the rules adopted by the State were not consistent with corresponding provisions of the Guidance. On September 14, 1999, EPA published in the Federal

Appendix C

Register a notice of and solicitation of public comment on its August 16, 1999, letter. 64 FR 49803. EPA has completed its review of the State of Indiana's response to, and all public comments on, the August 16, 1999, letter, and has determined that, with the exceptions described below, Indiana has adopted requirements consistent with all aspects of the Guidance. Specifically, Indiana has adopted requirements consistent with, and EPA is therefore approving those elements of the State's submissions which correspond to, the definitions in 40 CFR 132.2; the water quality criteria for the protection of aquatic life, human health and wildlife in tables 1-4 of Part 132; the methodologies for development of aquatic life criteria and values, bioaccumulation factors, human health criteria and values and wildlife criteria in Appendices B-D; the antidegradation policy in Appendix E; and, with the exceptions described below, the implementation procedures in Appendix F. As explained more fully below, Indiana has not adopted requirements consistent with the criteria for granting variances set forth in Paragraph 1 of Section C of Procedure 2 in Appendix F, requirements for including WQBELs in permits set forth in Paragraph 2 of Section F of Procedure 5 in Appendix F, and the provisions for determining reasonable potential and establishing water quality based effluent limitations for whole effluent toxicity set forth in Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F.

EPA's August 16, 1999, letter concluded that some of the provisions that EPA is now approving were inconsistent with the Guidance because authorized the State to act consistent with the Guidance, but provided inadequate assurance that the State would exercise its discretion

consistent with the Guidance. Subsequent to that letter, IDEM provided additional materials, including an Addendum to its Memorandum of Agreement with EPA regarding the State's approved NPDES program in which IDEM commits to always exercise its discretion under those provisions in a manner consistent with the Guidance. Pursuant to 40 CFR 123.44(c)(3) and 123.63(a)(4), the State is required to comply with commitments made in its MOA or risk EPA objection to permits and even program withdrawal. These materials have demonstrated to EPA that the State will implement its program (with exceptions identified below) consistent with the Guidance. The specific provisions that EPA is approving, and EPA's full rationale for approving these provisions, are set forth in the documents entitled "Indiana Provisions Approved as Being Consistent With the Guidance," "Analysis of Whether Indiana Has Adopted Requirements Consistent With the Guidance" and "Analysis of Steps Taken By Indiana in Response to EPA's 90-Day Letter."

EPA has determined that Indiana's provisions at 327 IAC 2-1.5-17(b), which allow IDEM to grant a variance from water quality standards if the permit applicant demonstrates that failure to grant the variance "will cause an undue hardship or burden upon the applicant," are inconsistent with the criteria for granting variances set forth at Paragraph 1 of Section C of Procedure 2 in Appendix F to 40 CFR Part 132. Specifically, the Guidance only allows variances based upon economic considerations if the failure to grant the variance "would result in substantial and widespread economic and social impact." EPA believes, and Indiana agrees, that it is possible that a failure to grant a variance could result in "an undue hardship or burden upon [a particular discharger]"

without also causing "substantial and widespread economic and social impact." Consequently, Indiana's provisions allow variances to be issued that relax water quality standards, and consequently permit conditions to meet standards, in instances where such a loosening of applicable requirements would not be permitted by the Guidance. Therefore, these provisions of Indiana's submission are not consistent with the Guidance.

EPA, therefore, disapproves of 327 IAC 2-1.5-17(b), and has determined that Paragraph 1 of Section C of Procedure 2 in Appendix F to 40 CFR Part 132 shall apply for discharges into the Great Lakes System in the State of Indiana. EPA notes that Indiana's "undue hardship or burden upon the applicant" criterion for granting a variance, as applied to municipal dischargers, may often be consistent with the "substantial and widespread social and economic impact" criterion in Paragraph 1.f of Section C of Procedure 2 in Appendix F to 40 CFR Part 132. This is because an undue hardship on the discharger (*i.e.*, the community served by the municipal discharger) may also constitute widespread social and economic impact. Consequently, EPA believes that specifying that Paragraph 1 of Section C of Procedure 2 in Appendix F to 40 CFR Part 132 applies to discharges into the Great Lakes System in the State of Indiana may, as a practical matter, not have a significant effect on the granting of variances for municipalities in Indiana. In any case, under today's rule, Indiana may only grant variances that meet the criteria specified in Procedure 2 in Appendix F to 40 CFR Part 132.

EPA has further determined that Indiana's provisions at 327 IAC 5-3-4.1(b)(1), which prevent Indiana from including

necessary WQBELs in permits simply because a variance application has been submitted, is inconsistent with Paragraph 2 of Section F of Procedure 5 in Appendix F to 40 CFR Part 132 and with 40 CFR 122.44(d). Under those federal provisions, WQBELs must be included in NPDES permits whenever there is reasonable potential that a discharge will cause or contribute to causing nonattainment of an existing water quality standard. The mere filing of a variance application does not change a water quality standard. Consequently, 327 IAC 5-3-4.1(b)(1), which prevents Indiana from including WQBELs when there is reasonable potential for a discharge to cause or contribute to causing nonattainment of an existing water quality standard where a permittee has applied for a variance from that standard, is not consistent with the Guidance and 40 CFR 122.44(d).

EPA, therefore, disapproves of 327 IAC 5-3-4.1(b)(1), and has determined that Paragraph 2 of Section F of Procedure 5 in Appendix F to 40 CFR Part 132 shall apply for discharges into the Great Lakes System in the State of Indiana.

EPA also has determined that Indiana's provisions at 327 IAC 5-2-11.5(c)(1) for determining reasonable potential for a discharge to cause or contribute to an exceedance of Indiana's WET requirements are inconsistent with Section D of Procedure 6 in Appendix F to 40 CFR Part 132.

As described above with respect to Michigan, EPA's procedure, in most cases, will project an effluent value greater than the maximum observed value to characterize the reasonable worst case effluent. Indiana's procedure, on the

other hand, uses the mean value of effluent data, further "discounted" by the fraction of tests exceeding the wasteload allocation. This both lessens the impact of observed toxicity on the calculation and fails to account for the reasonable possibility that effluent toxicity may exceed the level observed in the tests because sampling did not coincide with periods of maximum toxicity. An analysis of Indiana's procedure shows that those procedures often do not require a limit on WET where one would be required under the procedures in the Guidance. In fact, in some cases, Indiana's procedure would not require imposition of a WQBEL even where testing has showed actual, observed toxicity. This is clearly inconsistent with Section D of Procedure 6.

As discussed above with respect to Michigan and Ohio, Paragraph 1 of Section C of Procedure 6 requires that WQBELs be imposed whenever the WET reasonable potential procedures in Section D of Procedure 6 show that there is reasonable potential that a discharge will cause or contribute to causing an excursion above a State's numeric WET criterion or narrative criterion. Indiana's rules at 327 IAC 5-2-11.5(c), which specify when the permitting authority must include a WQBEL for WET, limits the permitting authority to using the WET reasonable potential procedures in Indiana's rules at 327 IAC 5-2-11.5(c)(1). Because 327 IAC 5-2-11.5(c) links establishment of WQBELs for WET to the Indiana WET reasonable potential procedures that EPA has determined are not consistent with Section D of Procedure 6 (i.e., the procedures in 327 IAC 5-2-11.5(c)(1)), 327 IAC 5-2-11.5(c) is not consistent with Paragraph 1 of Section C of Procedure 6.

EPA, therefore, disapproves of 327 IAC 5-2-11.5(c), and has determined that Paragraph 1 of Section C, and Section D, of Procedure 6 in Appendix F to 40 CFR Part 132 shall apply for discharges into the Great Lakes System in the State of Indiana.

4. The State of Illinois

On November 12, 1999, EPA issued a letter notifying the Illinois Environmental Protection Agency (IEPA) that, while the State of Illinois had generally adopted requirements consistent with the Guidance, EPA concluded that portions of the State's rules were not consistent with corresponding provisions of the Guidance. On December 9, 1999, EPA published in the Federal Register a notice of and solicitation of public comment on its November 12, 1999, letter. 64 FR 69019. EPA has completed its review of the State of Illinois' response to, and all public comments on, the November 12, 1999, letter, and has determined that, with one exception, Illinois has adopted requirements consistent with all aspects of the Guidance. Specifically, Illinois has adopted requirements consistent with, and EPA is therefore approving those elements of the State's submissions which correspond to, the definitions in 40 CFR 132.2; the water quality criteria for the protection of aquatic life, human health and wildlife in tables 1-4 of Part 132; the methodologies for development of aquatic life criteria and values, bioaccumulation factors, human health criteria and values and wildlife criteria in Appendices B-D; the antidegradation policy in Appendix E; and, with one exception described below, the implementation procedures in Appendix F. As explained more fully below, Illinois has not adopted requirements consistent with the

requirements governing total maximum daily loads in Procedure 3 in Appendix F.

EPA's November 12, 1999, letter, had concluded that some of the provisions that EPA is now approving were inconsistent with the Guidance because they authorized the State to act consistent with the Guidance, but provided inadequate assurance that the State would exercise its discretion consistent with the Guidance. Subsequent to that letter, Illinois provided additional materials, including an Addendum to its Memorandum of Agreement with EPA regarding the State's approved NPDES program in which IEPA commits to always exercise its discretion under those provisions in a manner consistent with the Guidance. Pursuant to 40 CFR 123.44(c)(3) and 123.63(a)(4), the State is required to comply with commitments made in its MOA or risk EPA objection to permits and even program withdrawal. These materials have demonstrated to EPA that the State will implement its program (with one exception identified below) consistent with the Guidance. The specific provisions that EPA is approving, and EPA's full rationale for approving these provisions, are set forth in the documents entitled "Illinois Provisions Approved as Being Consistent With the Guidance," "Analysis of Whether Illinois Has Adopted Requirements Consistent With the Guidance" and "Analysis of Steps Taken By Illinois in Response to EPA's 90-Day Letter."

EPA has determined that Procedure 3 in Appendix F to 40 CFR Part 132 shall apply with regard to development of total maximum daily loads (TMDLs) for the Great Lakes System in the State of Illinois because Illinois decided not

to adopt TMDL provisions for the Great Lakes System. Illinois did not adopt such provisions because EPA has indicated that it will be developing a TMDL for Lake Michigan and so Illinois does not believe that the State should be required to develop any TMDLs for the Great Lakes System. Today's action ensures that the provisions of Procedure 3 in Appendix F will apply in developing TMDLs in the Great Lakes System in the State of Illinois, regardless of who develops the TMDL. EPA notes that this promulgation has no effect on the reasonable potential procedures at 35 Ill. Adm. Code 309.141(h)(4), which EPA approves as being consistent with the reasonable potential procedures in Procedure 5 in Appendix F to 40 CFR Part 132, and which therefore apply in the Great Lakes System in the State of Illinois for purposes of developing preliminary effluent limitations in making reasonable potential determinations.

As noted above, EPA, in this notice, is not taking action to approve or disapprove portions of the States' Guidance submissions pertaining to NPDES permitting and water quality standards issues that are not addressed by the Guidance. While EPA is not taking action under Section 118 with regard to the following issue, EPA nevertheless wishes to describe its understanding with regard to one aspect of Illinois' submission that is not addressed by the Guidance. Specifically, Illinois' rules at 35 Ill. Adm. Code 352.700(a)(2) provide that, when a WQBEL is below the level of quantification, "[t]he analytical method adopted by the [Illinois Pollution Control] Board and specified in the permit shall be the method used for compliance assessment including enforcement actions."

EPA is concerned about this language because EPA believes, as a matter of law, that any credible evidence (subject to generally applicable rules of evidence), not just evidence generated by use of an analytical method specified in a permit, can be used in an enforcement action to establish that a violation of an effluent limitation has occurred. IEPA has clarified that 35 Ill. Adm. Code 352.700(a)(2) is only a limitation on the types of evidence that IEPA may use in an enforcement action; it does not place limits on the types of evidence that the federal government or third parties can use in an enforcement action or citizen suit. IEPA also has clarified that it does not intend to include the language of 35 Ill. Adm. Code 352.700(a)(2) in NPDES permits. Finally, IEPA is considering revising its rules to address EPA's concerns. While EPA is not, at this time, taking action to either approve or disapprove 35 Ill. Adm. Code 352.700(a)(2) as a modification of Illinois NPDES program, EPA notes that revisions to State NPDES programs do not become effective until approved by EPA. 40 CFR 123.62(b)(4).

D. Public Comments

EPA received a large number of public comments in response to its Federal Register notices of its receipt of the States' Guidance submissions and of the availability of EPA's letters to the States of Michigan, Ohio, Indiana and Illinois regarding their Guidance submissions. EPA has responded to each of those comments in a document entitled "EPA Responses to Comments Regarding the Great Lakes Guidance Submissions of the States of Michigan, Ohio, Indiana and Illinois' that has been included as part of the record in this matter. The following is a summary of EPA's responses to the most significant of these comments.

Appendix C

Comment: A number of commenters asserted that EPA's regulatory determinations are being made without affected parties having any chance to review the Agency's reasoning or to raise issues as to the validity of that reasoning, in violation of the Administrative Procedure Act and EPA's public participation regulations at 40 CFR 25.

Response: The final rule being promulgated today makes certain provisions of 40 CFR Part 132 applicable to discharges in certain States within the Great Lakes System. Those provisions were adopted after publication of a proposed rule for public comment. *See* 58 FR 20802 (April 16, 1993). EPA is not modifying those provisions, but merely making them effective in accordance with 40 CFR 132.5(f)(2). Therefore, the public had a full opportunity to comment on the contents of today's rule. Moreover, public comment was also received regarding EPA's review of the State submissions. EPA provided public notice of the availability of, and solicited comment on, the NPDES portions of these States' Guidance submissions in Federal Register notices dated March 2, 1998 and April 28, 1998. 63 FR 10221; 63 FR 23285. In Federal Register notices dated September 14, 1999, and December 9, 1999, EPA subsequently provided notice of the availability of letters to the States of Michigan, Ohio, Indiana and Illinois in which EPA provided (a) detailed explanations of the bases for its findings that certain States had not adopted provisions consistent with certain provisions of the Great Lakes Guidance and (b) its preliminary conclusions that, with the exception of those findings, the States had adopted provisions consistent with the Guidance. 64 FR 49803, 64 FR 69019. EPA also solicited comment on all aspects of those letters,

and has considered and responded to all comments received before taking today's final actions. Consequently, EPA has complied with all applicable public participation requirements.

Comment: A number of commenters raised questions regarding the basis for EPA's decisions to approve a State's provisions pertaining to a specific element of the Guidance where the State's provisions, on their face, do not plainly require the State's permitting or water quality standards authority to act in a manner consistent with the Guidance.

Response: EPA believes that these commenters' view is both unreasonable and contrary to EPA regulations governing the Agency's review of the State submissions. EPA regulations required each State to submit to EPA not only the criteria, methodologies, policies and procedures developed pursuant to the Guidance but also "general information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with" the Act and the Guidance, and "information on general policies which may affect their application and administration." 40 CFR 132.5(b)(1) and (4). Consistent with these regulations, EPA has not limited its review to solely the plain language of each State's criteria, methodologies, policies and procedures, but has considered the totality of the State's submission in determining whether it was consistent with the Guidance, including information regarding interpretation or implementation of a State's criteria, methodologies, policies and procedures.

Appendix C

As noted previously, the States were not required to adopt requirements that are identical to the Guidance. States' submissions can-and do-differ from the Guidance, and this difference is permissible provided the State's approach is consistent with (i.e., as protective as) the Guidance. Given the complexity of the States' submissions and EPA's review, it is not surprising that particular State provisions may be amenable to more than one interpretation or manner of application. Where a State's provision was either unclear or authorized the State to act consistent with the Guidance, but there was uncertainty as to whether the State would actually exercise its discretion consistent with the Guidance, EPA considered supplementary information to aid in determining the meaning and protectiveness of the State's provision vis-a-vis the Guidance. This information included, for example, States' legal interpretations of its criteria, methodologies, policies and procedures, or a State's position on how it would implement State law. For each of the States, clarification on the manner in which the State would exercise its discretion was provided on some issues in an addendum of the MOA with EPA governing its administration of the NPDES program. *See* 40 CFR 123.24. This MOA governs how each State will administer its NPDES program, and failure to comply with the terms of the MOA is grounds for EPA objection to a State permit and withdrawal of State's NPDES program. *See* 40 CFR 123.44(c)(3) and 123.63(a)(4).

Commenters suggest that EPA is required to ignore such supplementary information in its review and appear to believe that, simply because a State provision may be ambiguous or grants some flexibility to the State, EPA has no choice but to disapprove the provision as being inconsistent with the

Guidance. Nothing in EPA's regulations or in the CWA compels such a cabined exercise of judgment by EPA. Where the totality of a State's submission demonstrates that the State will administer its program consistent with the Guidance, EPA believes that it is appropriate to approve the submission.

Comment: A commenter disagrees that Indiana's variance procedures, which allow Indiana to grant variances based upon a finding that compliance with the existing water quality standard would have an "undue hardship or burden upon the applicant," is not consistent with the Guidance requirement that variances only be granted where compliance with the existing standard "would result in widespread economic and social impact." According to the commenter, Indiana has the ability to obtain and consider information regarding societal impacts in deciding whether to grant a variance and so Indiana's provisions are consistent with the Guidance. The commenter also argues that, even if Indiana's provisions are not consistent with the Guidance, EPA can apply its "substantial and widespread" test in deciding whether to approve of any variance that Indiana decides to grant under its applicant-specific test.

Response: The fact that Indiana "has the ability to obtain and consider information regarding societal impacts in deciding whether to grant a variance" does not change the fact that Indiana law requires that variances be allowed in circumstances where the Guidance does not allow for variances to be granted: i.e., where the failure to grant the variance would have an "undue hardship or burden upon the applicant" but not cause "widespread social and economic impact." Indiana's variance provisions, therefore, are not consistent with the Guidance.

Appendix C

With regard to the comment that EPA can apply the Guidance variance procedures in reviewing any variances that Indiana decides to grant, 40 CFR 132.4(a) requires that States "adopt requirements * * * that are consistent with * * * [t]he Implementation Procedures in Appendix F [to 40 CFR Part 132]." The affirmative obligation imposed on States by 40 CFR 132.4(a) to adopt such requirements would be rendered meaningless if EPA simply relied upon its approval/disapproval authorities as a basis to approve a State's provisions where the State does not interpret or implement a State provision in a manner that would be consistent with the Guidance.

Comment: One commenter believes that Indiana's provisions prohibiting it from imposing necessary WQBELs in NPDES permits simply because a variance application is pending are consistent with the Guidance. According to the commenter, "EPA has no authority, based on "protectiveness," to demand that the State issue a limit that will later need to be withdrawn because a variance has been granted. Moreover, * * * [u]nder the EPA rule, the State would be fully authorized to issue a limit while a variance application is pending and, at the same time, issue a compliance schedule that applies to that limit, so that the limit would not take effect until after the variance application is either granted * * * or denied. That would achieve exactly the same end as the process that is currently contained in the Indiana rules."

Response: Paragraph 2 of Section F of Procedure 5 in Appendix F to 40 CFR Part 132 and 40 CFR 122.44(d)(1) both require imposition of water quality based effluent limits

whenever there is reasonable potential for a discharge to cause or contribute to causing nonattainment of existing water quality standards. Nothing in those provisions, or anywhere else in the Clean Water Act or in EPA's regulations, creates an exception to this requirement to account for the fact that existing water quality standards may eventually change. Consequently, to the extent that 327 IAC 5-3-4.1(b)(1) prohibits Indiana from including WQBELs where there is reasonable potential that a discharge will cause or contribute to an exceedance of a standard simply because someone has merely requested a change to Indiana's existing water quality standards (but the standard has not yet been modified by issuance of the variance), it is inconsistent with Paragraph F.2 of Procedure 5 and 40 CFR 122.44(d)(1).

The commenter is correct that Indiana might be able to accomplish the same result in certain situations by granting the permittee a compliance schedule. However, under the Guidance, any such compliance schedule would have to meet the requirements governing compliance schedules in Procedure 9 in Appendix F to 40 CFR Part 132 (Indiana's Great Lakes compliance schedule provisions, which EPA is approving as being consistent with Procedure 9, are at 327 IAC 5-2-12.1). 327 IAC 5-3-4.1(b)(1), which prohibits Indiana from including WQBELs when a variance application has been applied for, is not limited only to situations when the requirements governing compliance schedules in Procedure 9 and 327 IAC 5-2-12.1 are met. Thus, 327 IAC 5-3-4.1(b) is not consistent with the Guidance.

Comment: A number of commenters believe that EPA should disapprove Indiana's rule at 327 IAC 5-2-11.7, which

the commenters assert allows Indiana to "downgrade" Indiana's historically held third tier, highest quality waters that were identified in the 1990 water quality standards approved by EPA as Outstanding State Resource Waters, which are Indiana's equivalent to Outstanding Natural Resource Waters (ONRW). These commenters also believe that EPA should disapprove Indiana's Guidance rules regarding mixing zones in Lake Michigan at 327 IAC 5-2-11.4(b)(2)(A) and (B), (b)4)(A)(iii) and (b)(4)(C), and (b)(5)-(7) because these sections allow a mixing zone in Lake Michigan contrary to the statewide ban on mixing zones in lakes at 327 IAC 2-1-4(c) of Indiana's EPA approved 1990 rules. The commenters believe that these changes constitute "downgrading" Indiana's standards for Lake Michigan.

Response: The term "downgrading" generally refers to a decision to modify a designated use where the current designated use cannot be attained for one of the reasons specified at 40 CFR 131.10(g). EPA's regulations at 40 CFR 131.10 place significant restrictions on a State's ability to engage in such "downgrading."

EPA's regulations at 40 CFR 131.12 and Appendix E to 40 CFR Part 132 describe various levels of antidegradation protections that must be afforded to water bodies. These various levels of protection, which are known as "Tier I," "Tier II" and "Tier III," are not "use designations," and so the restrictions placed on the States' ability to modify "designated uses" set forth at 40 CFR 131.10 do not apply to State decisions with regard to which "tier" of antidegradation protection should be afforded to particular water bodies. EPA further notes that EPA's regulations leave the question of

whether a particular water body constitutes a "Tier III" water (or ONRW) to the States' discretion. Consequently, EPA does not agree that it should disapprove Indiana's antidegradation provisions.

With regard to the commenters' concerns regarding Indiana's mixing zone provisions, the availability of mixing zones does not represent a change or "downgrade" in use and thus is not subject to 40 CFR 131.10. Nevertheless, while States generally have discretion to change mixing zone requirements, the States' mixing zone requirements must still ensure attainment of designated uses and, in the case of requirements applicable to the Great Lakes System, must be consistent with the Guidance. EPA believes that Indiana's mixing zone requirements do insure attainment of designated uses and are consistent with the Guidance. Consequently, EPA is approving those provisions of Indiana's rules, notwithstanding the possibility that those provisions of Indiana's rules may have relaxed Indiana's previously adopted mixing zone provisions.

Comment: Citing a May 4, 1999, letter from EPA to Indiana, a number of commenters believe that EPA should disapprove certain exemptions in Indiana's antidegradation rule at 327 IAC 5-2-11.7(c).

Response: The Guidance specifies certain minimum requirements which all Great Lakes States must include in their antidegradation policies and implementation procedures that are specific to protecting the waters of the Great Lakes System. Specifically, the Guidance establishes minimum requirements for States' antidegradation policies which are

largely identical to those of 40 CFR 131.12, and implementation requirements that are specific to BCCs. Indiana's policy and implementation procedures are consistent with the requirements identified in the Guidance. To the extent that Indiana's revised rules contain changes addressing other elements of the State's antidegradation policy not addressed by the Guidance (i.e., procedures addressing non-BCCs), those elements are outside the scope of this action and will be addressed in a separate proceeding.

Comment: EPA received numerous comments asserting that Section D of Procedure 6 in Appendix F, the WET reasonable potential procedure, was not valid because not all WET data sets appear to be lognormally distributed (as readily acknowledged by EPA). Based on this observation, the commenters conclude that Section D of Procedure 6 is scientifically indefensible and, therefore, EPA must accept the other procedures submitted by the States of Ohio, Michigan, and Indiana. These commenters further assert that EPA has no basis for disapproving these State procedures as not being consistent with the Guidance. (The same comments were made about the Illinois procedure even though it is based primarily on the Guidance procedure and is being approved by EPA. Accordingly, the discussion below does not relate to Illinois.) EPA believes that these commenters misunderstand the scope of the scientific defensibility provision of the Guidance. They also fail to refute EPA's conclusion that Ohio's, Michigan's and Indiana's procedures are not consistent with the Guidance.

The Guidance procedure for using effluent data to calculate a projected effluent quality (PEQ) for determining

when a WET limit is needed Section D of Procedure 6 estimates an upper bound effluent value (95th percentile) by multiplying the maximum observed effluent value (expressed as toxic units) by a factor designed to take into account long-term effluent variability and the number of data available to make the projection. The size of the multiplying factor is determined by the number of data points in the data set, the variability of the effluent, the assumed distribution of the data, and the chosen confidence level for capturing the true 95th percentile (95 percent in the case of Table F6-1). Except in rare cases where there are large amounts of data, the projected 95th percentile will be greater than maximum observed effluent value.

Some commenters contended that Section D of Procedure 6-which uses multiplying factors that are based on the assumption that data are lognormally distributed-is scientifically indefensible within the meaning of 40 CFR 132.4(h), and that the States are therefore free to adopt other approaches. Section 132.4(h) allows States to adopt alternative methodologies or procedures different from those contained in the Guidance where a State demonstrates that a methodology or procedure is not scientifically defensible. EPA included this flexibility to address pollutants identified in the future for which some of the methodologies or procedures may not be technically appropriate. 58 Fed. Reg. 20843 (April 16, 1993). *See also*, Supplemental Information Document for the Water Quality Guidance for the Great Lakes System (March 23, 1995) (SID) at 58-59. No party contends that new pollutants pose unique technical attributes that render application of the existing WET methodologies or procedures invalid. Rather, these commenters simply contend

that certain aspects of Procedure 6 promulgated by EPA are technically unsound and overly conservative. However, Section 132.4(h) is not a vehicle for parties to challenge anew the Guidance itself. The CWA requires the States to adopt policies, standards and procedures that are consistent with the Guidance promulgated by EPA. CWA § 118(c)(2)(C). EPA is reviewing State submissions to determine their consistency with the Guidance but has not reopened any provision of the Guidance in our review. The public had a full opportunity to provide its views on Procedure 6 during the rulemaking establishing the Guidance, and the time period for challenging the Guidance has passed. *See* CWA § 509(b). Therefore, none of the comments provide any basis for allowing the States to establish alternative methodologies and procedures pursuant to 40 CFR 132.4(h) to address whole effluent toxicity.

Even if Section 132.4(h) were relevant, none of the States has actually proposed an alternative approach of projecting effluent toxicity that attempts to meet even the basic parameters of the Guidance. While the States have flexibility to adopt approaches that make different assumptions about the distribution of WET data than is assumed in Procedure 6, no one has presented EPA with an analysis identifying a different distribution or statistical method that fits WET data better, either in general or in a particular case. More fundamentally, however, the procedures submitted by Ohio, Michigan and Indiana do not address in any manner the underlying premise of Procedure 6-that effluent quality is variable and, therefore, a method for assessing WET data must account for the likelihood that the maximum value in a particular data set is less than the true maximum that is likely to be experienced by the environment as a result of the

discharge. In evaluating the potential for a discharge to cause or contribute to an exceedance of water quality standards, EPA believes it prudent to employ a procedure that minimizes the likelihood of misclassifying a discharge as not needing an effluent limitation, given the potential in such circumstances for unacceptable adverse impacts on the aquatic resource. Because the purpose of the PEQ reasonable potential procedure is to extrapolate from typically small data sets a reasonable worst case effluent quality that could be expected over the life of a permit, using a conservative assumption is in keeping with the purpose of the procedure. The reasonable potential determination is intended to allow the permitting authority to make a decision that will protect water quality with a high degree of confidence in the face of uncertainty and with a relatively small data set.

Rather than providing alternative methods of accounting for the uncertainty associated with small data sets by using an alternative mechanism that more precisely predicts likely maximum toxicity levels (*e.g.*, alternative multipliers or "safety factors"), the Michigan and Indiana procedures make no attempt to extrapolate likely toxicity levels (i.e., they lack any safety factor whatsoever). Indeed, these States' procedures move in the opposite direction by averaging the observed effluent data in some fashion and applying either a mandatory or optional adjustment downward based on a "failure" rate. Ohio's procedure is more complex and less predictable, but it also provides for "discounting" observed WET data rather than applying a safety factor. Thus, not only do these procedures fail entirely to consider the potential of the discharge to cause or contribute to an exceedance taking into account long-term effluent variability and the fact that a

small number of data sets may not capture the worst case effluent quality, they actually allow a finding of "no reasonable potential" where available data has indicated unacceptable toxicity. EPA does not consider these approaches to be either as protective as the Guidance, or in accordance with applicable national regulations (40 CFR 22.44(d)(1)).

EPA also received comments that EPA should find Ohio's weight-of-evidence approach for determining reasonable potential for WET as protective as the Guidance. These commenters support the Ohio approach as superior in considering all data regarding the toxicity of an effluent and note especially a feature of the Ohio procedure that they say would use biosurvey data as a substitute for the multiplier in Table F6-1 when considering WET data.

EPA does expect permitting authorities to consider all relevant information in determining whether reasonable potential exists. EPA believes that this is best accomplished by considering each line of evidence regarding the effect of an effluent on the environment separately and without differential weighting of data drawn from different sources. As discussed in the Technical Support Document for Water Quality-based Toxics Control (EPA/505/2-90-001, March 1991) (TSD) and reflected in paragraph 3 of Section F of Procedure 5 in Appendix F, the chemical-specific, bioassessment, and WET characterization approaches each have unique as well as overlapping attributes, sensitivities, and program applications, no single approach for detecting impact should be considered uniformly superior to any other approach (*See* Chapter 3.1.3, p. 49). Consistent with this

principle, data showing an effect or potential for an effect is sufficient to require effluent limits and the results of one assessment technique should not be used to contradict or overrule the results of the other techniques that indicate the need for an effluent limit. This is especially appropriate when the task at hand is not only to identify existing problems but to predict the possibility of future adverse impacts and impose effluent limits to prevent those adverse impacts from occurring.

EPA recognizes some merit in the position that biological data can reduce the uncertainties about the effect of the discharge and thus could serve a similar purpose as the multipliers or "safety factors" used in the Guidance procedure. Taken as a whole, however, the Ohio procedure has the significant shortcoming discussed above of "discounting" WET data. Specifically, where biological data are unavailable to corroborate effluent toxicity data, Ohio's procedure would require that the maximum observed toxicity be at least three times greater than the expected toxicity limit, that the average toxicity exceed one-third the expected effluent limit, and that more than more than 30 percent of the test results exceed a projected wasteload allocation before it would be likely that a limit will be imposed. Where biological data are present to corroborate effluent data, it is not clear, as the commenter asserts, that a limit would be required if the maximum observed effluent value exceeded the projected effluent limit. In this situation, Ohio's procedure still could require that the maximum observed effluent value be greater than the projected wasteload allocation, that the average of the effluent test results exceed half the expected effluent limit for acute toxicity and two-thirds the expected

effluent limit for chronic toxicity, and that more than 30 percent of the effluent values exceed the expected toxicity limit before a limit is imposed. Thus, Ohio's procedures will not necessarily require a limit even in situations where the effluent toxicity is observed in excess of the expected toxicity limit. As discussed above, such a procedure is inconsistent with the Guidance.

Another set of comments asserted that EPA must examine a State's whole approach to addressing WET and determine whether it reduces effluent toxicity to a similar extent as EPA's approach, rather than simply focusing on whether the State's procedures will result in imposition of effluent limits for WET in all situations where the Great Lakes Guidance would require imposition of such limits.

It is unclear how the commenter believes EPA's analysis is deficient and why a different analysis would show a different result. Certainly, the procedure that determines whether or not a permit includes a WQBEL for a particular pollutant or parameter (the reasonable potential procedure) is a critical element for determining the level of protection that will be achieved when implementing a water quality standard. Where a reasonable potential procedure is not as protective as the Guidance, a State's WET program cannot be considered to achieve the same level of protection as the Guidance.

EPA also notes that in addition to the requirements of the Procedure 6 of the Guidance itself, Section 301(b)(1)(C) of the Clean Water Act requires "limitation[s] * * * necessary to meet any applicable water quality standard." Moreover,

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EPA's regulations implementing Section 301(b)(1)(C) at 40 CFR 122.44(d)(1)(iv) and (v) require that NPDES permits contain "effluent limits for whole effluent toxicity" or chemical-specific limits in lieu of WET limits, whenever there is reasonable potential that a discharge will cause or contribute to an in-stream excursion above a numeric criterion for WET or a narrative criterion of no toxics in toxic amounts. Therefore, the CWA and EPA's implementing regulations require permitting authorities to impose WQBELs for WET when there has been a reasonable potential finding, and EPA does not believe it would be consistent with the CWA and EPA regulations to approve an alternative approach that omits this fundamental requirement. EPA notes that, in appropriate cases, a permitting authority can include a compliance schedule for the WQBEL that would allow for additional monitoring and identification and reduction of toxicants, followed by a reassessment of the need for a limit or the identification of a specific toxicant that could be subject to a WQBEL rather than WET.

Some commenters contended that EPA's actions with respect to Indiana's, Michigan's and Ohio's WET reasonable potential procedures were not consistent with statements by EPA that permitting authorities retain the right to determine whether data is relevant and valid.

EPA agrees that permitting authorities have the right to exercise reasonable discretion to reject unrepresentative or invalid data in making reasonable potential determinations. EPA does not agree, and the commenter fails to explain why it believes, that EPA's actions with respect to Indiana's, Michigan's and Ohio's WET reasonable potential procedures

conflict with that position. Section D of Procedure 6 is neutral with respect to the validity of particular pieces of WET data (*e.g.*, were the quality assurance/quality control requirements of the method correctly followed) or whether that data is representative of the discharge (*e.g.*, was the sample taken during normal operations of the facility). It is designed to work on the assumption that the permittee has submitted data the permitting authority agrees are valid and representative of the discharge. If the commenter is saying that States have the discretion to determine that valid, representative data that show effluent toxicity are irrelevant in determining whether a WET limit is needed, EPA disagrees.

PA is nonetheless aware that there has been considerable concern about the possibility that variability in WET test results could erroneously indicate toxicity. EPA recently addressed this issue in the document, "Understanding and Accounting for Method Variability in Whole Effluent Toxicity (WET) Applications Under the NPDES Program" (EPA 833-R-00-003, June 2000). This document clarifies several issues regarding WET variability and reaffirms EPA's earlier guidance and recommendations published in the Technical Support Document for Water Quality-Based Toxics Control (TSD, USEPA 1991). The document discusses analysis of WET data that shows WET test method precision is comparable to chemical-specific method precision. Significantly, the document recommends that, rather than adjusting the reasonable potential procedures, WET test method variability be minimized by adhering to the EPA test methods (especially the quality assurance/quality control procedures), representative sample collection, and other recommendations provided in the document related to

evaluating the validity of specific WET test results. The Federal Register notice announcing the availability of this document and the document itself may be viewed or downloaded on the Internet at http://www.epa.gov/owm/npdes.htm.

E. Consequences of Today's Action

As a result of today's action, the Guidance provisions specified in today's rule apply in the Great Lakes System in the States specified in the rule until such time as a State adopts requirements consistent with the specific Guidance provisions at issue, and EPA approves those State requirements and revises the rule so that the provisions no longer apply in that State.

II. "Good Cause" Under the Administrative Procedure Act

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553 (b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without publishing a notice of proposed rulemaking. EPA has determined that there is good cause for promulgating today's rule final without publishing a notice of proposed rulemaking because EPA finds it unnecessary and contrary to the public interest. Today's rule does not promulgate any new regulatory provisions. Rather, in accordance with the procedures in 40 CFR 132.5(f), today's rule identifies the provisions of Part 132 promulgated previously by EPA that shall apply to discharges in certain States within the Great Lakes System. Those provisions have

already been subject to a notice of proposed rulemaking, and publication of a new proposed rule is therefore unnecessary. *See* 58 FR 20802 (April 16, 1993). In addition, while EPA's approval/disapproval decisions described in this notice do not constitute rulemaking, EPA has nonetheless received substantial public comment on these decisions. *See* 63 FR 10221 (March 2, 1998) and 63 FR 23285 (April 28, 1998) (notices of receipt of State Guidance submissions and requests for comment); 64 FR 49803 (September 14, 1999), and 64 FR 69019 (December 9, 1999) (notices of letters identifying inconsistencies and requests for comment). EPA also believes the public interest is best served by fulfilling the CWA's requirements without further delay and publication of a notice of proposed rulemaking therefore would be contrary to the public interest. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. Because the agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, as described in Section II, above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), or to Sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). In addition, because this action does not promulgate any new requirements, but only makes certain existing provisions of

40 CFR Part 132 effective in several States, it does not impose any new costs. The costs of Part 132 were considered by EPA when it promulgated that regulation. Therefore, today's rule does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in Sections 203 and 204 of UMRA, or significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by Section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement

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Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register . A major rule cannot take effect until 60 days after it is published in the Federal Register. This rule is not a major rule as defined by *5 U.S.C. 804*(2). This rule will be effective September 5, 2000.**

List of Subjects in 40 CFR Part 132

Administrative practice and procedure, Great Lakes, Indian-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: July 31, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth above, EPA amends 40 CFR Part 132 as follows:

Appendix C

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

1. The authority citation for part 132 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

2. Text is added to § 132.6 to read as follows:

§ 132.6 — Application of part 132 requirements in Great Lakes States and Tribes.

(a) Effective September 5, 2000, the requirements of Paragraph C.1 of Procedure 2 in Appendix F of this Part and the requirements of paragraph F.2 of Procedure 5 in Appendix F of this Part shall apply to discharges within the Great Lakes System in the State of Indiana.

(b) Effective September 5, 2000, the requirements of Procedure 3 in Appendix F of this Part shall apply for purposes of developing total maximum daily loads in the Great Lakes System in the State of Illinois.

(c) Effective September 5, 2000, the requirements of Paragraphs C.1 and D of Procedure 6 in Appendix F of this Part shall apply to discharges within the Great Lakes System in the States of Indiana, Michigan and Ohio.

[FR Doc. 00-19792 Filed 8-3-00; 8:45 am]

(3)

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No. 05-1095

In the Supreme Court of the United States

INDIANA WATER QUALITY COALITION, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Under Section 118(c)(2)(A) and (C) of the Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, 86 Stat. 816, as amended, the Environmental Protection Agency (EPA) was required to "provide guidance to the Great Lakes States on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System," and to review the Great Lakes States' proposed standards, policies, and implementation procedures for "consisten[cy] with such guidance." 33 U.S.C. 1268(c)(2)(A) and (C). In 1995, following notice to the public and an opportunity to comment, EPA issued the required guidance. In 2000, after reviewing the State of Indiana's proposed standards, policies, and implementation procedures for consistency with the guidance, EPA disapproved one of Indiana's implementation procedures. The question presented is as follows:

Whether EPA's decision to disapprove Indiana's implementation procedure was reasonable and consistent with the 1995 guidance.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 411 F.3d 726.

JURISDICTION

The judgment of the court of appeals was entered on June 16, 2005. A petition for rehearing was denied on November 22, 2005 (Pet. App. 17a-18a). The petition for a writ of certiorari was filed on February 21, 2006 (the Tuesday following a holiday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Water Pollution Control Act Amendments of 1972 (Clean Water Act or CWA), Pub. L. No. 92-500, 86 Stat. 816, as amended (33 U.S.C. 1251 *et seq.*),

prohibit the discharge of any pollutant into "navigable waters" except in accordance with the Act. 33 U.S.C. 1311(a), 1362(12)(A). "The Clean Water Act anticipates a partnership between the States and the Federal Government, animated by a shared objective: 'to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'" *Arkansas* v. *Oklahoma*, 503 U.S. 91, 101 (1992) (quoting 33 U.S.C. 1251(a) (1988)). Under the CWA, the Environmental Protection Agency (EPA) "provides States with substantial guidance in the drafting of water quality standards." *Ibid.* (citing 40 C.F.R. Pt. 131 (1991)). "If the EPA recommends changes to the standards and the State fails to comply with that recommendation, the Act authorizes the EPA to promulgate water quality standards for the State." *Ibid.* (citing 33 U.S.C. 1313(c) (1988)).

The National Pollutant Discharge Elimination System (NPDES) is established by Section 402 of the CWA, 33 U.S.C. 1342, and "requires dischargers to obtain permits that place limits on the type and quantity of pollutants that can be released into the Nation's waters." *South Fla. Water Mgmt. Dist.* v. *Miccosukee Tribe of Indians*, 541 U.S. 95, 102 (2004). NPDES permits impose limits based on available technologies, 33 U.S.C. 1311(b), and any more stringent limits necessary to meet water quality standards, 33 U.S.C. 1311(b)(1)(C). Longstanding NPDES regulations require water quality-based limits whenever a discharge would "cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard." 40 C.F.R. 122.44(d)(1)(i); see *id.* § 122.44(d)(1)(iv). "Section 402(b) authorizes each State to establish 'its own permit program for discharges into navigable waters within its

jurisdiction.'" *Arkansas*, 503 U.S. at 102 (quoting 33 U.S.C. 1342(b)).

In 1990, Congress amended Section 118 of the CWA to address the problem of pollutant discharges into the Great Lakes System. 33 U.S.C. 1268 (2000 & Supp. III 2003); see *American Iron & Steel Inst.* v. *EPA*, 115 F.3d 979, 989 (D.C. Cir. 1997) ("Congress was attempting to create a uniform set of requirements for water pollution in the Great Lakes."). Section 118 directs EPA to "provide guidance to the Great Lakes States on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System," 33 U.S.C. 1268(c)(2)(A); see 33 U.S.C. 1268(c)(2)(B), and it requires the Great Lakes States to "adopt water quality standards, antidegradation policies, and implementation procedures * * * which are consistent with such guidance," 33 U.S.C. 1268(c)(2)(C). If and to the extent that a Great Lakes State fails to adopt standards, policies, and procedures that are consistent with the guidance provided by EPA, EPA is directed to promulgate federal standards, policies, or procedures that will then apply to discharges in the relevant State. See 33 U.S.C. 1268(c)(2)(C); 40 C.F.R. 132.5(f)(2); Pet. App. 3a.

In 1995, following a notice-and-comment procedure, EPA issued the required guidance. *Final Water Quality Guidance for the Great Lakes System*, 60 Fed. Reg. 15,366 (Guidance); see Pet. App. 3a. The Guidance has three basic parts. First, it outlines criteria and methodologies for protecting aquatic life, human health, and wildlife from toxic pollutants. See 40 C.F.R. Pt. 132, Tbls. 1-4, Apps. A-D. Second, it prescribes antidegradation procedures to protect existing high-quality waters within the Great Lakes System. See 40 C.F.R.

Pt. 132, App. E. Third, the Guidance establishes requirements to ensure more consistent implementation of water-quality criteria in regulating individual discharges of toxic pollutants into the System. See 40 C.F.R. Pt. 132, App. F.

The third part of the Guidance establishes an implementation procedure under which an NPDES permitting authority determines whether a facility's permit requires a discharge limitation to control whole effluent toxicity (WET) to a level that will assure attainment of water quality standards. See Pet. App. 2a. The term "WET" is defined under pre-existing NPDES regulations as the combined toxic effect of individual chemicals in a discharge measured directly using test organisms in a laboratory. See 40 C.F.R. 122.2; *Edison Elec. Inst.* v. *EPA*, 391 F.3d 1267, 1268-1269 (D.C. Cir. 2004) (describing test procedures). In general terms, the Guidance's implementation procedure for determining the need for a WET limit (a) starts with the maximum observed toxicity value derived from laboratory testing of a facility's effluent; (b) applies a statistical multiplier to that maximum value to account for the likelihood that the facility did not collect samples at the precise moment when the combined toxic effect of the facility's wastestream was at its highest; (c) adjusts downward to reflect any available dilution in the receiving water; and (d) compares the resulting value to the amount of toxicity that a healthy water body can sustain (*i.e.*, the applicable WET criteria in the water quality standard). See 40 C.F.R. Pt. 132, App. F, Procedure 6, Sec. D; Pet. App. 3a-4a. If the permitting authority projects that the discharge is likely to have a greater toxic effect on the receiving water of the Great Lakes System than the acceptable level of toxicity identified in the standard, then it may autho-

rize the discharge only with an NPDES permit that includes an effluent limitation for WET.

The Guidance further provides that, "[f]or any pollutant other than those in Table 5 of this part for which the State * * * demonstrates that a methodology or procedure in this part is not scientifically defensible," a Great Lakes State shall "[a]pply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws." 40 C.F.R. 132.4(h)(2). WET is not one of the pollutants listed in Table 5 of Part 132. At the same time that it promulgated the Guidance, EPA also issued a Supplementary Information Document (SID). C.A. App. 302. The SID explains that "[t]he reason for this [scientific-indefensibility] exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures in the final Guidance may not be technically appropriate." *Id.* at 308. The SID also expresses EPA's intent "that the exclusion be limited to each specific element of the Guidance that [is] demonstrated to be inappropriate if applied to a specific situation." *Id.* at 309. The Guidance itself notes that

> [t]he scientific, policy and legal basis for EPA's development of each section of the final Guidance * * * is set forth in the preamble, [SID], Technical Support Documents, and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing State * * * water quality programs in the Great Lakes for consistency with this part.

40 C.F.R. 132.1(b).

2. In 2000, after reviewing the standards, policies, and implementation procedures proposed by the State

of Indiana and other Great Lakes States, including public notice and opportunity for comment, EPA approved a large majority of the state proposals. See Pet. App. 19a-26a, 34a-40a; 63 Fed. Reg. 10,221 (1998); 64 Fed. Reg. 49,803 (1999); C.A. App. 494-507, 628-633, 650, 657-659, 679-686, 690-696, 704. EPA disapproved Indiana's proposed WET implementation procedure, however, concluding that it was inconsistent with the Guidance. See Pet. App. 38a-40a. EPA explained that Indiana's proposed procedure, whose application turns on the *average* toxicity of different samples rather than on the maximum observed toxic value, "both lessens the impact of observed toxicity on the calculation and fails to account for the reasonable possibility that effluent toxicity may exceed the level observed in the tests because sampling did not coincide with periods of maximum toxicity." *Id.* at 39a. EPA further observed that the proposed Indiana procedures "often do not require a limit on WET where one would be required under the procedures in the Guidance," and that, "in some cases, Indiana's procedure would not require imposition of a [permit limit for WET] even where testing has showed actual, observed toxicity." *Ibid.*; see C.A. App. 658 (Indiana's WET implementation procedure "require[s] multiple failures" of a toxicity test before the facility's NPDES permit must contain a WET limit).

In the course of its decision, EPA considered and rejected Indiana's contention that EPA's own WET implementation procedure is scientifically indefensible, and that the State's procedure therefore was not required to be consistent with the applicable Guidance provisions. Pet. App. 52a-61a. EPA explained that the scientific-indefensibility exclusion set forth in 40 C.F.R. 132.4(h) is intended "to address pollutants identified in